

US3482284 (Prod: Synexus Clinical Research US, Inc. – Orlando)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:50:35

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US3482284

Form: Participant Creation

Data signed: (b) (4) 24 Mar 2021 01:46:02

Generated On: 09 Jun 2021 17:50:35

Participant ID

US3482284

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

US3482284

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
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	False
Black	True
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) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 15:39:05

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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) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	HEART MURMUR
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	ROTATOR CUFF SURGERY, LEFT
Start date (dd MMM yyyy)	20 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	20 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	IRREGULAR HEART RHYTHM
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	TORN TENDON, LEFT SHOULDER
Start date (dd MMM yyyy)	20 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	20 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	CHRONIC KIDNEY DISEASE STAGE IIIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	ATRIAL SEPTAL DEFECT, WITH REPAIRS IN 1986 & 1997
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	HIV PROPHYLAXIS
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 (12)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	DVT LEFT LEG (POST L HIP ARTHROPLASTY)
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	OSTEOARTHRITIS (MULTIPLE JOINTS, MULTIPLE SURGERIES)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	HIP ARTHROPLASTY, LEFT
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	HERPES SIMPLEX 2 INFECTION
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	CORONARY ARTERY DISEASE WITH CALCIFIED LESION
Start date (dd MMM yyyy)	UN JAN 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	GOUT, L TOE
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:55 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:55
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	228.7 lb
BMI (<i>xxx.x</i>)	30.23642 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	106 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482284

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:39:05

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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 REALTOR

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:39:05

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

What was the date of randomization? (dd MMM yyyy) 16 OCT 2020

What was the participant's randomization number? 147186

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) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

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)	16 OCT 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

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)	16 OCT 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 13:30
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 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) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:39:05

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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) 16 OCT 2020

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

Treatment Date and Time (derived) 16 OCT 2020 13:00

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

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was the sample collected?

Yes ☒

No ☐

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

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	16 OCT 2020 12:35
Nasopharyngeal Swab 2	No		

US3482284

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 16 OCT 2020 13:28

PC Open Date & Time 16 OCT 2020 13:20

PC Close Date & Time 16 OCT 2020 15:50

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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	17 OCT 2020 01:02
PC Open Date & Time	16 OCT 2020 16:45
PC Close Date & Time	17 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 17:18

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

18 OCT 2020 19:10

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 17:51

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 OCT 2020 21:10

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 20:06

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 7

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

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

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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

22 OCT 2020 20:55

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 13:29

PC Open Date & Time

16 OCT 2020 13:20

PC Close Date & Time

16 OCT 2020 15:50

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 01:03

PC Open Date & Time

16 OCT 2020 16:45

PC Close Date & Time

17 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 17:19

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 19:11

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 17:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 21:11

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 20:06

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 20:56

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 13:30
PC Open Date & Time	16 OCT 2020 13:20
PC Close Date & Time	16 OCT 2020 15:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

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

No ☒

Yes ☐

PC Time stamp	17 OCT 2020 01:04
PC Open Date & Time	16 OCT 2020 16:45
PC Close Date & Time	17 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 17:21
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:13
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 17:52
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 20:07
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 20:57
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

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)	4 DEC 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	4 DEC 2020 10:45
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3482284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 DEC 2020

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

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

NOT ELIGIBLE DUE TO UNSTABLE CARDIAC STATE

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3482284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 DEC 2020

Collection time (00:00-23:59)

11:15 (24 HR)

Collection date and time (derived)

4 DEC 2020 11:15

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Collection date (dd MMM yyyy)			4 DEC 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:12	4 DEC 2020 11:12
Nasopharyngeal Swab 2	No		

US3482284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted? Yes ☐
No ☒

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

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

Comments

If Contact Not Made, please provide Comments _____

US3482284

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted? Yes ☐
No ☒

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

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

Comments

If Contact Not Made, please provide Comments _____

US3482284

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:04

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 DEC 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 14:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 DEC 2020

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

US3482284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 DEC 2020
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	21 DEC 2020 14:25

US3482284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:39:05

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 18:13:23
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 00:16:07
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 11:10:17

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 00:11:12

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 13:17:20
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 00:01:57
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 12:32:17

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 14:10:22

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 22:28:36
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	14 FEB 2021 08:50:54
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:49:21

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 19:28:49

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 03:51:54

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 00:02:53

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 19:35:13

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	29 MAR 2021 12:42:23
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 12:17:11

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 07:15:48

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 12:06:04

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 11:32:04

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 05:59:28

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 208

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Patient Cloud Open Date & Time	24 APR 2022 00:01
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Patient Cloud Close Date & Time	28 APR 2022 23:59
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US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2022 00:01
Patient Cloud Close Date & Time	08 DEC 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2022 00:01
Patient Cloud Close Date & Time	22 DEC 2022 23:59

US3482284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:50:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	02 MAR 2021 19:30:03

US3482284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 01:46:07

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 01:46:07

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 01:46:07

Generated On: 09 Jun 2021 17:50:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 01:46:07

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:20:19

Generated On: 09 Jun 2021 17:50:35

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

US3482284

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:20:19

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

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 _____

US3482284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3482284

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3482284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3482284

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Date of Contact	12 NOV 2020
Time of Contact	16:00
Date and Time of Contact (derived)	12 NOV 2020 16:00
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>

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

309 of 3801

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	31 OCT 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	01 NOV 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)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	02 NOV 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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	03 NOV 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"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	04 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	05 NOV 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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	6 NOV 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"/>

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 NOV 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"/>

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EAB) (1725)

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Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 NOV 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 NOV 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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 NOV 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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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 checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 01:46:04

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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 checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

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 checked="" 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"/>

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	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	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Date of Visit 13 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 13 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
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)	

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

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

Visit date (dd MMM yyyy)	13 NOV 2020
--------------------------	-------------

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

Folder OID	SICKD1
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US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 10:34
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3482284

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3482284

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

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

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

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3482284

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

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>)	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3482284

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3482284

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 12:40
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3482284

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 14:39
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3482284

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

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

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.

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

Form: Exposure

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 13:53 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 13:53

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

What was the frequency of the study treatment dosing? ONCE

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

13:05 (24 HR)

Collection date and time (derived)

15 JAN 2021 13:05

US3482284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

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)	13:08
Collection Date and Time (derived)	15 JAN 2021 13:08

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

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 01:46:07

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 01:46:07

Generated On: 09 Jun 2021 17:50:35

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3482284

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482284

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 FEB 2021
Collection time (00:00-23:59)	12:55 (24 HR)
Collection date and time (derived)	12 FEB 2021 12:55

US3482284

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

AEID	USA-US106-2020-MRNA-1273-P30 1000002
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	31 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

Number of Days in ICU	1
Persistent or significant disability or incapacity	True
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 checked="" type="radio"/> Not Applicable <input 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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SHORTNESS OF BREATH & IMPAIRED CARDIAC FUNCTION (CHF)
Narrative	

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

SUBJECT WITH CHEST PAIN
BEGINNING 28OCT2020.
INITIALLY THOUGHT IT WAS
INDIGESTION DUE TO DINNER
FROM PREVIOUS NIGHT. IT
PERSISTED TO 29OCT2020, AND
PT STARTED HAVING
DIZZINESS AND SHORTNESS OF
BREATH WITH CLIMBING A
LADDER FOR WORK, SO
SUBJECT WENT TO ED. EKG
REVEALED ST ELEVATION MI
AND LABS SHOWED ELEVATED
TROPONIN (MAX 45.5). WAS
TREATED WITH NTG, ASAS,
AND HEPARIN IV. SUBJECT
UNDERWENT EMERGENT
CARDIAC CATHETERIZATION
WITH UNSUCCESSFUL
THROMBECTOMY &
ANGIOPLASTY TO TOTALLY
OCCLUDED MID RCA. HE WAS
TRANSFERRED TO ICU FOR
ONGOING CARE. WAS TREATED
WITH INTEGRILIN DRIP WITH
CONTINUED BASELINE
STATINS, BETA BLOCKER, AND
AMLODIPINE. WAS NOTED TO
HAVE RENAL IMPAIRMENT ON
ADMISSION LABS. COVID PCR
WAS NEGATIVE. PARTICIPANT
IMPROVED DURING
ADMISSION AND WAS D/C'D TO
RETURN TO ATLANTA FOR F/U
WITH REGULAR
CARDIOLOGIST FOR FURTHER
MANAGEMENT.

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)	1

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	SHORTNESS OF BREATH, WORSENING
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	7 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTE ON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE PRIOR VISIT IN CLINIC AND

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

HAD AN ILLNESS VISIT HERE 13
NOV 2020.
UPDATE: PARTICIPANT SEEN
ON 4 DEC 2020 FOR DAY 29
VISIT; NO IP GIVEN. MEDICAL
HX CLARIFIED AND UPDATED.
STILL WAITING FOR RECORDS
FROM 3RD HOSPITALIZATION.
PT STILL WITH ONGOING
TACHYPNEA (26 RESP AT REST)
AND +1 PITTING LE EDEMA.

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)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE ON CHRONIC SYSTOLIC HEART FAILURE
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)	5 NOV 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)	4 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	7 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:25:43

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Number of Days in ICU	1
Persistent or significant disability or incapacity	True
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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SEQUELA IS NEW DX OF CHF (CHRONIC). HAS INTERMITTENT EXACERBATIONS WITH EDEMA, ET AL.

Narrative

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTE ON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE PRIOR VISIT IN CLINIC AND

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

HAD AN ILLNESS VISIT HERE 13
NOV 2020. SEE MEDICAL
RECORDS FROM
HOSPITALIZATION SENT FOR
REVIEW.
UPDATE: PARTICIPANT SEEN
ON 4 DEC 2020 FOR DAY 29
VISIT; NO IP GIVEN. MEDICAL
HX CLARIFIED AND UPDATED.
STILL WAITING FOR RECORDS
FROM 3RD HOSPITALIZATION.
PT STILL WITH ONGOING
TACHYPNEA (26 RESP AT REST)
AND +1 PITTING LE EDEMA.

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)	1

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE CORONARY SYNDROME, EXACERBATION
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)	16 NOV 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)	20 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 03:25:43

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Number of Days in ICU	4
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 (4)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

SUBJECT BEGAN HAVING CHEST PAIN AFTER SAFETY CALL WAS COMPLETED ON 16NOV2020 AND SOUGHT MEDICAL ATTENTION IN ED. TEAM WAS NOTIFIED ON 19NOV2020 OF ADMISSION TO HOSPITAL FOR EVALUATION OF "ARRHYTHMIA" AND "FLUTTER" PER SUBJECT DESCRIPTION. MEDICAL RECORDS PENDING. 10-DEC-2020 UPDATE AFTER REVIEW OF MEDICAL RECORDS: AFTER 16-NOV-2020 PRESENTATION TO ED WITH CHEST PAIN, SUBJECT WAS FOUND TO HAVE ACUTE CORONARY SYNDROME CAUSING ACUTE SYSTOLIC HEART FAILURE. HE WAS FOUND TO HAVE NEW CARDIOMEGALY AND MULTIFOCAL PARENCHYMAL OPACITIES CONCERNING FOR PULMONARY EDEMA. DUE TO LEUKOCYTOSIS (ALTHOUGH HE WAS AFEBRILE WITH NEGATIVE BLOOD CULTURES), HE WAS TREATED EMPIRICALLY FOR PNEUMONIA IN ED. HE WAS ALSO FOUND TO HAVE ST ELEVATION WITH TACHYCARDIA (HR IN 150S)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

WITH UNDERLYING ATRIAL
FIBRILLATION. STARTED ON
NITROGLYCERIN AND HEPARIN
DRIP. HE WAS ALSO LOADED
WITH AMIODARONE. UNABLE
TO COMPLETE CV MRI DUE TO
CLAUSTROPHOBIA DURING
ADMISSION. SYMPTOMS HAD
RESOLVED BY 20-NOV-2020
AND WAS DISCHARGED
STABLE. HE WILL CONTINUE
WITH ASA, PLAVIX AND
XARELTO, BETA BLOCKER,
STATIN. WILL FOLLOW UP
WITH OUTPATIENT
CARDIOLOGIST.

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)	1

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE
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)	16 NOV 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)	14 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

	Unknown	<input type="radio"/>
Number of Days in ICU		4
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 checked="" type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		True
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input type="radio"/>
	Recovered/Resolved with Sequelae	<input checked="" type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	19FEB 2021 UPDATE: WAS CLEARED BY CARDIOLOGIST ON 14JAN 2021 FOR REVAX. ARRHYTHMIA CONTROLLED ON CONTINUED CARDIAC MEDS. DEEMED STABLE, NEW BASELINE ESTABLISHED.	

Narrative

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

SUBJECT HAD INCREASED
DYSPNEA AND NEW CHEST
PAIN ON 16-NOV-2020 IN WHICH
HE PRESENTED TO ED. HE WAS
TACHYCARDIC WITH HR IN
150S WITH UNDERLYING
ATRIAL FLUTTER. HE WAS
STARTED ON HEPARIN DRIP
AND UNDERWENT
AMIODARONE LOADING
DURING ADMISSION. PLANS TO
FOLLOW UP WITH OUTPATIENT
ABLATION WITHIN 2 MONTHS.
CONTINUES TREATMENT FOR
CONDITION.

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)	1

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	PAROXYSMAL ATRIAL FLUTTER
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)	05 NOV 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)	14 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)	05 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	07 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

Number of Days in ICU	3
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 checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	NEW BASELINE A FIB WITH PAROXYSMAL A FLUTTER - CONTROLLED ON AMIODARONE.

Narrative

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:25:43

Generated On: 09 Jun 2021 17:50:35

SUBJECT PRESENTED TO ED
WITH GRADUAL ONSET OF
INTERMITTENT CHEST PAIN
AND DYSPNEA ON EXERTION.
FOUND TO BE IN ATRIAL
FLUTTER IN ED.
CARDIOVERSION WAS
PLANNED DURING ADMISSION
BUT DUE TO DELAY IN
INITIATING PROCEDURE,
SUBJECT DID NOT WANT TO
WAIT AND LEFT HOSPITAL
AMA. BEING FOLLOWED BY
CARDIOLOGY.

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)	1

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Mar 2021 01:46:03

Generated On: 09 Jun 2021 17:50:35

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication METOPROLOL XL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 (3)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 (4)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication TRIAMETERENE HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5/25

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) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication DESCOVY

Prophylaxis Yes ☒
No ☐

Indication HIV PROPHYLAXIS

Dose per administration 25/200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<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) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication RED VOLT EXTREME FAT
BURNER

Prophylaxis Yes ☐
No ☒

Indication WEIGHT LOSS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication IMMUNE SUPPORT VITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication TREATMENT OF CLOT -
ASSOCIATED WITH AE #1

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" 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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN - ASSOCIATED
WITH AE #1

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication AE#1 (MYOCARDIAL INFARCTION)

Dose per administration 324

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 (13)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐
No ☒

Indication AE#1 (MYOCARDIAL INFARCTION)

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA AND BIPOLAR DISORDER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
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"/>

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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 (16)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA -
ASSOCIATED WITH AE #1

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication SHORTNESS OF BREATH,
WORSENING

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication XARELTO

Prophylaxis Yes ☒
No ☐

Indication CLOT PREVENTION -
ASSOCIATED WITH AE #3

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 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)		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) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN - ASSOCIATED
WITH AE #1

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (21)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication SHORTNESS OF BREATH,
WORSENING

Dose per administration 3700

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

If dose unit is Other, specify UNITS

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 (21)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication SUSPECTED PNEUMONIA -
ASSOCIATED WITH AE #3

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)		5 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication SUSPECTED PNEUMONIA -
ASSOCIATED WITH AE #3

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	7 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication CLOT PREVENTION -
ASSOCIATED WITH AE #3

Dose per administration 17.4

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

If dose unit is Other, specify UNITS PER KG PER HOUR

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 (24)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication SHORTNESS OF BREATH,
WORSENING

Dose per administration 324

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 (25)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication DIURETIC - ASSOCIATED WITH
AE #3

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL
FLUTTER/FIBRILLATION -
ASSOCIATED WITH AE #5

Dose per administration 400

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication ADENOSINE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL
FLUTTER/FIBRILLATION -
ASSOCIATED WITH AE #5

Dose per administration 6-12

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 (28)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN PROTOCOL -
ASSOCIATED WITH AE #4

Dose per administration 324

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 (29)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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Name of Medication CEFRIAXONE

Prophylaxis Yes ☐
No ☒

Indication SUSPECTED PNEUMONIA
ASSOCIATED WITH AE #4

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" 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)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication DIGOXIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL
FLUTTER/FIBRILLATION
ASSOCIATED WITH AE #5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒
No ☐

Indication TO PREVENT GI UPSET
RELATED TO MEDICATION
ADMINISTRATION -
ASSOCIATED WITH AE #4

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication DIURETIC - ASSOCIATED WITH
AE #4

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication DIURETIC - ASSOCIATED WITH
AE #4

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication HEPARIN DRIP

Prophylaxis Yes ☒
No ☐

Indication CLOT PREVENTION
ASSOCIATED WITH AE #5

Dose per administration 18.4

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

If dose unit is Other, specify UNITS/KG/HOUR

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 CONTINUOUS INFUSION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION ASSOCIATED
WITH AE #4

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION ASSOCIATED
WITH AE #4

Dose per administration 50

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

If dose unit is Other, specify ML/HR

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 CONTINUOUS INFUSION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION ASSOCIATED
WITH AE #4

Dose per administration 12.5

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION ASSOCIATED
WITH AE #4

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN RELATED TO ACS
ASSOCIATED WITH AE #4

Dose per administration 5-10

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

If dose unit is Other, specify MCG/MIN

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 CONTINUOUS INFUSION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 08 Apr 2021 16:23:24

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Name of Medication ODANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA - ASSOCIATED WITH
AE #4

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA RELATED TO
LASIX ADMINISTRATION
ASSOCIATED WITH AE #4

Dose per administration 40

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

If dose unit is Other, specify MEQ

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 (42)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)		08 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication BIPOLOAR DISORDER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN NOV 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication INTEGRILIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify CONTINUOUS DRIP

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication ACUTE ON CHRONIC SYSTOLIC
HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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)		3 FEB 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"/>

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNITS

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)

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 08 Apr 2021 16:23:24

Generated On: 09 Jun 2021 17:50:35

	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 MAY 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN MAY 2017		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Mar 2021 01:46:04

Generated On: 09 Jun 2021 17:50:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Mar 2021 01:46:03

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 OCT 2020	CARDIAC CATHETERIZATION WITH ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTION	Adverse Event	
17 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
19 NOV 2020	CARDIOVASCULAR MRI	Adverse Event	
5 NOV 2020	ELECTROCARDIOGRAM	Adverse Event	
6 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
29 OCT 2020	ELECTROCARDIOGRAM	Adverse Event	
29 OCT 2020	CHEST XRAY	Adverse Event	
29 OCT 2020	STANDARD OF CARE BLOOD WORK FOR CHEST PAIN PROTOCOL	Adverse Event	
16 NOV 2020	BLOOD CULTURES	Adverse Event	

US3482284

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 24 Mar 2021 01:46:05

Generated On: 09 Jun 2021 17:50:35

Date of dosing discontinuation (dd MMM yyyy) 04 DEC 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent	#1
by participant, Protocol deviation, or Other, specify	#2
	#3
	#4
	#5
	#6

US3482284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:50:35

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	02/NOV/2020 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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	09/NOV/2020 19:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	11/NOV/2020 13:41
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	12/NOV/2020 15:06
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	17/NOV/2020 14:34
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	18/NOV/2020 21:05
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	02/DEC/2020 09:47
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	09/DEC/2020 09:30
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	11/DEC/2020 09:34
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	11/DEC/2020 10:46
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	
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.	False

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	14/DEC/2020 09:01
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (13)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	23/DEC/2020 11:05
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (14)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	06/JAN/2021 14:52
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (15)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	25/JAN/2021 16:52
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (16)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	01/FEB/2021 10:55
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (17)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	19/FEB/2021 14:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (18)

Data signed: (b) (4) 24 Mar 2021 01:46:06

Generated On: 09 Jun 2021 17:50:35

SAEID	USA-US106-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	17
Date of submission (Pre-filled from custom function)	19/FEB/2021 15:03
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

US3482284 (Prod: Synexus Clinical Research US, Inc. – Orlando)

US3482284

Form: Participant Creation

Generated On: 09 Jun 2021 17:50:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'US3482284'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 17:52:46

US3482284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:07:35

US3482284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '09 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 17:52:47

US3482284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:07:35

US3482284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'SCRN'	System	09 Oct 2020 19:07:35

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 17:52:48

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '62'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'YEARS'	System	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '62'	System	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:50:35

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:46:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:43:18
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Oct 2020'	System	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2020'	System	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:46:52
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:43:20
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 21:20:16
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:46:53
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:43:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:46:55
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:43:24
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:46:57
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:43:25
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:46:59
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:43:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:47:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:43:29
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 17:52:47

US3482284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:50:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'I'	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:50:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:50:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:08:01

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:36:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:36:54
Data point term sent to Coder	System	16 Oct 2020 20:17:22
User entered 'Hypertension'	(b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2014'	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2014'	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Oct 2020 09:38:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:38:04
Data point term sent to Coder	System	16 Oct 2020 20:18:23
User entered 'Heart Murmur'	(b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'un UNK 1988'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 1988'	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '1988'	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:54
Data point term sent to Coder	System	16 Oct 2020 20:19:29
User entered 'ACE Inhibitor Allergy'	(b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2009'	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2009'	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:17:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:17:55
Data point term sent to Coder	System	04 Dec 2020 21:52:16
Coding entries removed.	(b) (4), (b) (6)	04 Dec 2020 21:52:06
User entered 'ROTATOR CUFF SURGERY, LEFT' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 21:52:06
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	29 Oct 2020 12:52:11
' (Site from DM).		
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	26 Oct 2020 19:57:34
' answered with 'Updated medical history to reflect that surgery was completed because of torn tendon' (Site from DM).		
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	26 Oct 2020 09:38:52
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:39:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:39:37

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EAB) (1725)

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	16 Oct 2020 20:20:32
User entered 'Rotator Cuff Surgery'	(b) (4), (b) (6)	16 Oct 2020 20:19:48

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '20 Feb 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '20 Feb 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Feb 2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Feb 2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:39:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:39:37
Data point term sent to Coder	System	16 Oct 2020 20:20:33
User entered 'Insomnia'	(b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2019'	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2019'	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Oct 2020 09:40:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:40:09
Data point term sent to Coder	System	16 Oct 2020 20:21:35
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2018'	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2018'	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heart rate irregular - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:40:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:40:10
Data point term sent to Coder	System	16 Oct 2020 20:21:35
User entered 'Irregular Heart Rhythm'	(b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 1995'	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '1995'	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Rupture tendon - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 01:24:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 01:24:47
Data point term sent to Coder	System	04 Dec 2020 20:00:50
Coding entries removed.	(b) (4), (b) (6)	04 Dec 2020 20:00:46
User entered 'TORN TENDON, LEFT SHOULDER' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 20:00:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Tendon rupture - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:57:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:57:27
Data point term sent to Coder	System	26 Oct 2020 19:56:17
User entered 'Torn Tendon'	(b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '20 Feb 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '20 Feb 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Feb 2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Feb 2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
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.	Coder Import (b) (4)	18 Nov 2020 07:21:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 07:21:01
Data point term sent to Coder	System	17 Nov 2020 21:16:17
User entered 'CHRONIC KIDNEY DISEASE stage IIIa'	(b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Congenital cardiovascular anomaly therapeutic procedures, PT: Atrial septal defect repair, LLT: Atrial septal defect repair - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 03:58:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 03:58:59
Data point term sent to Coder	System	04 Dec 2020 20:04:52
User entered 'ATRIAL SEPTAL DEFECT, WITH REPAIRS IN 1986 & 1997'	(b) (4), (b) (6)	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 1998'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 1998'	System	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '1998'	System	04 Dec 2020 20:04:32

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Antiinfective therapies, PT: Prophylaxis against HIV infection, LLT: Prophylaxis against HIV infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Dec 2020 20:07:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 20:07:59
Data point term sent to Coder	System	04 Dec 2020 20:07:01
User entered 'HIV PROPHYLAXIS'	(b) (4), (b) (6)	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2016'	System	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2016'	System	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:06:07

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip arthroplasty - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Dec 2020 04:52:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 04:52:06
Data point term sent to Coder	System	04 Dec 2020 20:06:59
User entered 'DVT LEFT LEG (POST L HIP ARTHROPLASTY)'	(b) (4), (b) (6)	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2012'	System	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2012'	System	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2012'	System	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2012'	System	04 Dec 2020 20:06:50

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:57:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:57:53
Data point term sent to Coder	System	04 Dec 2020 20:08:02
User entered 'OSTEOARTHRITIS (MULTIPLE JOINTS, MULTIPLE SURGERIES)'	(b) (4), (b) (6)	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 20:07:28

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:13:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:13:23
Data point term sent to Coder	System	04 Dec 2020 20:10:03
User entered 'HIP ARTHROPLASTY, LEFT'	(b) (4), (b) (6)	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2012'	System	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2012'	System	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2012'	System	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2012'	System	04 Dec 2020 20:09:12

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:14:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:14:09
Data point term sent to Coder	System	04 Dec 2020 20:10:03
User entered 'HIP ARTHROPLASTY, RIGHT'	(b) (4), (b) (6)	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2014'	System	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2014'	System	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2014'	System	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2014'	System	04 Dec 2020 20:09:44

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 21:03:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 21:03:01
Data point term sent to Coder	System	04 Dec 2020 21:01:47
User entered 'VITAMIN D DEFICIENCY'	(b) (4), (b) (6)	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN Jan 2019'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2019'	System	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2019'	System	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:00:53

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:11:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:11:56
Data point term sent to Coder	System	04 Dec 2020 21:01:47
User entered 'HERPES SIMPLEX 2 INFECTION'	(b) (4), (b) (6)	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2002'	System	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2002'	System	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:01:26

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Dec 2020 21:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 21:04:02
Data point term sent to Coder	System	04 Dec 2020 21:02:48
User entered 'PROSTATE CANCER'	(b) (4), (b) (6)	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2008'	System	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2008'	System	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2008'	System	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2008'	System	04 Dec 2020 21:02:06

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Reproductive system and breast disorders, HLG: 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)	04 Dec 2020 21:33:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 21:33:01
Data point term sent to Coder	System	04 Dec 2020 21:32:08
User entered 'ERECTILE DYSFUNCTION'	(b) (4), (b) (6)	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2008'	System	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2008'	System	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:31:44

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Arteriosclerosis coronary artery, LLT: Coronary artery calcification - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 04:50:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 04:50:05
Data point term sent to Coder	System	04 Dec 2020 21:33:09
User entered 'CORONARY ARTERY DISEASE WITH CALCIFIED LESION'	(b) (4), (b) (6)	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN Jan 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2020'	System	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2020'	System	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:32:15

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:07:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 05:07:03
Data point term sent to Coder	System	04 Dec 2020 21:33:08
User entered 'GOUT, L TOE'	(b) (4), (b) (6)	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN Dec 2019'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Dec 2019'	System	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2019'	System	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:32:44

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and 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)	21 Jan 2021 01:53:09
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and 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 'Updated con meds to reflect that Seroquel is taken for treatment of insomnia and bipolar disorder' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 16:30:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and 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)	12 Jan 2021 07:11:31
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 21:35:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 21:35:10
Data point term sent to Coder	System	04 Dec 2020 21:34:10
User entered 'BIPOLAR DISORDER'	(b) (4), (b) (6)	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2006'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2006'	System	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2006'	System	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	04 Dec 2020 21:33:15

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Elbow operation, LLT: Elbow operation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 16:28:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 16:28:59
Data point term sent to Coder	System	04 Dec 2020 21:48:15
User entered 'ORTHOPEDIC REPAIR, LEFT ELBOW'	(b) (4), (b) (6)	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2010'	System	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2010'	System	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2010'	System	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2010'	System	04 Dec 2020 21:48:07

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Elbow operation, LLT: Elbow operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Dec 2020 16:28:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:28:59
Data point term sent to Coder	System	04 Dec 2020 21:49:15
User entered 'ORTHOPEDIC REPAIR, R ELBOW'	(b) (4), (b) (6)	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2016'	System	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2016'	System	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'Jan 2016'	System	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:50:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '2016'	System	04 Dec 2020 21:49:13

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '13:55'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '9 Oct 2020 13:55'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '73' in	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '228.7' lb	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '30.23642'	System	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'kg/m2'	System	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
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)	
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 by data change (Site from System).	System	09 Oct 2020 19:18:03
User entered '96.9' F reason for change: Data Entry Error	System	09 Oct 2020 19:18:03
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).	(b) (4), (b) (6)	09 Oct 2020 19:17:07
User entered '96.7' F	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '83'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'bpm'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'breaths/min'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '148'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'mmHg'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
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).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 10:41:58
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) (6)	09 Oct 2020 19:17:32
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).		09 Oct 2020 19:17:07
User entered '106'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'mmHg'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04

US3482284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:49:33
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:08:13

US3482284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:49:33
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:08:13

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

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 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Realtor'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:07:50
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:50:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User closed query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	(b) (4) System	16 Oct 2020 16:07:50
User opened query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	16 Oct 2020 16:07:41
User entered 'Resident in a community with ongoing person to person transmission'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'VISIT1'	System	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Oct 2020 16:43:28

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '147186'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Oct 2020 16:43:28

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Oct 2020 16:43:28

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:50:35

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:53:30
DataPoint set to visible.	System	09 Oct 2020 19:14:41

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '11:50'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '16 Oct 2020 11:50'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '90'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'bpm'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'breaths/min'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '138'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '85'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '13:30'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '16 Oct 2020 13:30'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '90'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'bpm'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'breaths/min'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '125'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '80'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:49:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:53:41

US3482284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:49:59
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:53:41

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '13:00'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '16 Oct 2020 13:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'ONCE'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '12:30'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '16 Oct 2020 12:30'	System	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:50:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '12:35'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '16 Oct 2020 12:35'	System	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:54:27

US3482284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	16 Oct 2020 16:54:27

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:27:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523' User entered 'Yes (Y)'	System	16 Oct 2020 17:28:38
	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523' User entered '98.0'	System	16 Oct 2020 17:28:38
	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:16', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523'	System	16 Oct 2020 17:28:38
User entered 'No (N)'	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:32', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523' User entered '16 Oct 2020 13:28'	System	16 Oct 2020 17:28:38
	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 13:20'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 15:50'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:01:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff' User entered 'Yes (Y)'	System	17 Oct 2020 05:02:38
	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff' User entered '97.6'	System	17 Oct 2020 05:02:38
	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff' User entered 'No (N)'	System	17 Oct 2020 05:02:38
	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:35', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff' User entered '17 Oct 2020 01:02'	System	17 Oct 2020 05:02:38
	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 16:45'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 2'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:07', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678' User entered 'Yes (Y)'	System	17 Oct 2020 21:18:58
	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:25', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678' User entered '97.8'	System	17 Oct 2020 21:18:58
	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:32', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678' User entered 'No (N)'	System	17 Oct 2020 21:18:58
	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:55', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678' User entered '17 Oct 2020 17:18'	System	17 Oct 2020 21:18:58
	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 3'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:09:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465' User entered 'Yes (Y)'	System	18 Oct 2020 23:10:48
	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:32', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465' User entered '97.6'	System	18 Oct 2020 23:10:48
	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465' User entered 'No (N)'	System	18 Oct 2020 23:10:48
	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:47', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465' User entered '18 Oct 2020 19:10'	System	18 Oct 2020 23:10:48
	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 4'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:09', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8' User entered 'Yes (Y)'	System	19 Oct 2020 21:51:34
	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8' User entered '97.4'	System	19 Oct 2020 21:51:34
	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:27', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8' User entered 'No (N)'	System	19 Oct 2020 21:51:34
	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:31', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8' User entered '19 Oct 2020 17:51'	System	19 Oct 2020 21:51:34
	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 5'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:29', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806' User entered 'Yes (Y)'	System	21 Oct 2020 01:10:53
	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:37', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806' User entered '97.7'	System	21 Oct 2020 01:10:53
	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:42', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806'	System	21 Oct 2020 01:10:53
User entered 'No (N)'	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:46', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806' User entered '20 Oct 2020 21:10'	System	21 Oct 2020 01:10:53
	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 6'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:05:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec' User entered 'Yes (Y)'	System	22 Oct 2020 00:06:11
	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:05:56', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec' User entered '97.9'	System	22 Oct 2020 00:06:11
	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec'	System	22 Oct 2020 00:06:11
User entered 'No (N)'	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:09', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec' User entered '21 Oct 2020 20:06'	System	22 Oct 2020 00:06:11
	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 7'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:29', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec' User entered 'Yes (Y)'	System	23 Oct 2020 00:55:52
	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec' User entered '97.3'	System	23 Oct 2020 00:55:52
	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec'	System	23 Oct 2020 00:55:52
User entered 'No (N)'	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:50', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec' User entered '22 Oct 2020 20:55'	System	23 Oct 2020 00:55:52
	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:56', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered 'None (1)'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23' User entered 'No (N)'	System	16 Oct 2020 17:29:51
	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:10', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered 'No (N)'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:33', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered 'None (1)'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23' User entered '16 Oct 2020 13:29'	System	16 Oct 2020 17:29:51
	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 13:20'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 15:50'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4' User entered 'None (1)'	System	17 Oct 2020 05:03:19
	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:53', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4' User entered 'No (N)'	System	17 Oct 2020 05:03:19
	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4' User entered 'No (N)'	System	17 Oct 2020 05:03:19
	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4' User entered 'None (1)'	System	17 Oct 2020 05:03:19
	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:16', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4' User entered '17 Oct 2020 01:03'	System	17 Oct 2020 05:03:19
	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 16:45'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 2'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb' User entered 'None (1)'	System	17 Oct 2020 21:19:54
	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:10', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb' User entered 'No (N)'	System	17 Oct 2020 21:19:54
	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:15', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb' User entered 'No (N)'	System	17 Oct 2020 21:19:54
	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:42', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb' User entered 'None (1)'	System	17 Oct 2020 21:19:54
	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:52', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb' User entered '17 Oct 2020 17:19'	System	17 Oct 2020 21:19:54
	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 3'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:56', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered 'None (1)'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered 'No (N)'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98' User entered 'No (N)'	System	18 Oct 2020 23:11:35
	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:27', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered 'None (1)'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:31', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98' User entered '18 Oct 2020 19:11'	System	18 Oct 2020 23:11:35
	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 4'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe' User entered 'None (1)'	System	19 Oct 2020 21:52:11
	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:54', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe' User entered 'No (N)'	System	19 Oct 2020 21:52:11
	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:58', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe' User entered 'No (N)'	System	19 Oct 2020 21:52:11
	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:02', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe' User entered 'None (1)'	System	19 Oct 2020 21:52:11
	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:07', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe' User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:52:11
	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 5'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:52', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered 'None (1)'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered 'No (N)'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:02', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered 'No (N)'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered 'None (1)'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:11', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered '20 Oct 2020 21:11'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 6'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:14', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3' User entered 'None (1)'	System	22 Oct 2020 00:06:42
	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3' User entered 'No (N)'	System	22 Oct 2020 00:06:42
	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:28', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3' User entered 'No (N)'	System	22 Oct 2020 00:06:42
	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:37', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3' User entered 'None (1)'	System	22 Oct 2020 00:06:42
	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:40', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3' User entered '21 Oct 2020 20:06'	System	22 Oct 2020 00:06:42
	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 7'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:58', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb' User entered 'None (1)'	System	23 Oct 2020 00:56:35
	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:10', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb' User entered 'No (N)'	System	23 Oct 2020 00:56:35
	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:18', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb' User entered 'No (N)'	System	23 Oct 2020 00:56:35
	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb' User entered 'None (1)'	System	23 Oct 2020 00:56:35
	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:33', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb' User entered '22 Oct 2020 20:56'	System	23 Oct 2020 00:56:35
	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered 'None (0)'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered 'None (0)'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered 'None (0)'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:24', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered 'None (0)'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:35', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered 'None (0)'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered 'None (0)'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:49', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered 'No (N)'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492' User entered '16 Oct 2020 13:30'	System	16 Oct 2020 17:31:01
	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 13:20'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 15:50'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered 'None (0)'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:26', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered 'None (0)'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered 'None (0)'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:33', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered 'None (0)'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:36', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered 'None (0)'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered 'None (0)'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:04:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered 'No (N)'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:04:05', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f' User entered '17 Oct 2020 01:04'	System	17 Oct 2020 05:04:09
	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '16 Oct 2020 16:45'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 2'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered 'None (0)'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:12', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered 'None (0)'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered 'None (0)'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:37', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered 'None (0)'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:43', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered 'None (0)'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered 'None (0)'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:21:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered 'No (N)'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:21:28', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered '17 Oct 2020 17:21'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 3'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:41', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:44', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:51', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:55', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:12:31', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:12:55', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:13:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'No (N)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:13:12', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered '18 Oct 2020 19:13'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 4'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:12', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:15', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:18', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:24', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:26', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:43', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'No (N)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:46', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 5'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:15', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:18', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:21', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:23', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:27', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:36', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'No (N)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered '20 Oct 2020 21:11'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 6'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:51', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered 'None (0)'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:54', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered 'None (0)'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:59', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered 'None (0)'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:04', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered 'None (0)'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:09', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered 'None (0)'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered 'None (0)'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:24', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered 'No (N)'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:29', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906' User entered '21 Oct 2020 20:07'	System	22 Oct 2020 00:07:31
	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 7'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:41', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:51', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:53', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:57:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'No (N)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:57:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered '22 Oct 2020 20:57'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:50:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:50:24
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:26:00

US3482284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	23 Oct 2020 20:26:00

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 17:21:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 17:21:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
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) System	06 Nov 2020 23:08:32
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 by data change (Site from System).	System	06 Nov 2020 23:08:32
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:08:32
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	06 Nov 2020 23:08:02
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 17:21:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 17:21:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:38

US3482284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:35:15
User entered 'I'	System	06 Nov 2020 23:08:38

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:32:25
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:08:55

US3482284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	06 Nov 2020 23:08:55

US3482284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:36:04

US3482284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User closed query 'Per CDM re-query: Response noted; However please clarify in query response why the visit 2 performed out of window. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 04:11:34
Query 'Per CDM re-query: Response noted; However please clarify in query response why the visit 2 performed out of window. Thank you.' answered with 'VIST PERFORMED OOW BEC PARTICIPANT WAS HOSPITALIZED DURING WINDOW AND WAS ONLY WELL ENOUGH TO COME FOR VISIT ON 4 DEC 2020. HAS ONGOING SOB AND CARDIOPULMONARY COMPROMISE FROM HEART ATTACK AND HEART FAILURE. SEE SAE NOTES. STILL AWAITING D/C NOTES FROM LAST ADMISSION.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 00:13:14
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 10:35:16
User opened query 'Per CDM re-query: Response noted; However please clarify in query response why the visit 2 performed out of window. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 10:35:14
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'out of window visit completed - protocol deviation completed' (Site from System).	Hollie Macenczak (b) (4)	04 Dec 2020 23:36:25
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	04 Dec 2020 23:36:04
User entered '4 Dec 2020'	Hollie Macenczak (b) (4)	04 Dec 2020 23:36:04

US3482284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Dec 2020 00:13:22
User entered 'Home (Home)'	Hollie Macenczak (b) (4)	04 Dec 2020 23:36:04

US3482284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'VISIT2'	System	04 Dec 2020 23:36:04

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Pre-Dose (PREDOSE)'	Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '4 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '10:45'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '4 Dec 2020 10:45'	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '97.8' F	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Oral (Oral)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '86'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'bpm'	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '26'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'breaths/min'	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '128'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '83'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Post-Dose (POSTDOSE)'	Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:37:39

US3482284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:45

US3482284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '4 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:37:45

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
	(b) (4)	
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Hollie Macenczak (b) (4)	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Not eligible due to unstable cardiac state'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:39:32

US3482284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:52

US3482284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '4 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:52

US3482284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '11:15'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:39:52

US3482284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '4 Dec 2020 11:15'	System	04 Dec 2020 23:39:52

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:50:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '4 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hollie Macenczak (b) (4)	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '11:12'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '4 Dec 2020 11:12'	System	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hollie Macenczak (b) (4)	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered empty.	System	04 Dec 2020 23:40:09

US3482284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	04 Dec 2020 23:40:12

US3482284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	04 Dec 2020 23:40:12

US3482284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:24

US3482284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:24

US3482284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:24

US3482284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:24

US3482284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:28

US3482284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	22 Dec 2020 22:13:28

US3482284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:39

US3482284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:39

US3482284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:39

US3482284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:39

US3482284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:42

US3482284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	22 Dec 2020 22:13:42

US3482284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:49

US3482284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:49

US3482284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:49

US3482284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:49

US3482284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:13:54

US3482284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	22 Dec 2020 22:13:54

US3482284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:04

US3482284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '21 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:04

US3482284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Clinic (Clinic)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:04

US3482284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'VISIT3'	System	22 Dec 2020 22:14:04

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '21 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '14:05'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '21 Dec 2020 14:05'	System	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '98.1' F	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Oral (Oral)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '77'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'bpm'	System	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '26'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'breaths/min'	System	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '108'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '69'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'mmHg'	System	22 Dec 2020 22:14:37

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25

US3482284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25

US3482284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:43

US3482284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '21 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:14:43

US3482284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:15:03

US3482284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '21 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:15:03

US3482284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered '14:25'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:15:03

US3482284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '21 Dec 2020 14:25'	System	22 Dec 2020 22:15:03

US3482284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:39:06
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:15:07

US3482284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered '1'	System	22 Dec 2020 22:15:07

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-17T18:12:51', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a13d789b-a097-46bf-9b47-bba279faf048'	System	17 Dec 2020 23:13:26
User entered 'No (N)'	System	17 Dec 2020 23:13:26

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-17T18:13:02', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a13d789b-a097-46bf-9b47-bba279faf048'	System	17 Dec 2020 23:13:26
User entered 'No (N)'	System	17 Dec 2020 23:13:26

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-17T18:13:23', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a13d789b-a097-46bf-9b47-bba279faf048' User entered '17 Dec 2020 18:13:23'	System	17 Dec 2020 23:13:26
	System	17 Dec 2020 23:13:26

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-20T00:15:42', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'f1aa2d50-9c55-4fd5-ad06-8f3c21961d0c' User entered 'No (N)'	System	20 Dec 2020 05:16:10
	System	20 Dec 2020 05:16:10

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-20T00:15:54', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'f1aa2d50-9c55-4fd5-ad06-8f3c21961d0c'	System	20 Dec 2020 05:16:10
User entered 'No (N)'	System	20 Dec 2020 05:16:10

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-20T00:16:07', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'f1aa2d50-9c55-4fd5-ad06-8f3c21961d0c' User entered '20 Dec 2020 00:16:07'	System	20 Dec 2020 05:16:10
	System	20 Dec 2020 05:16:10

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-27T11:09:41', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aa82b2b5-6a74-40c9-a7db-d3ba51d7e16c' User entered 'No (N)'	System	27 Dec 2020 16:10:19
	System	27 Dec 2020 16:10:19

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-27T11:09:54', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aa82b2b5-6a74-40c9-a7db-d3ba51d7e16c' User entered 'No (N)'	System	27 Dec 2020 16:10:19
	System	27 Dec 2020 16:10:19

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2020-12-27T11:10:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aa82b2b5-6a74-40c9-a7db-d3ba51d7e16c' User entered '27 Dec 2020 11:10:17'	System	27 Dec 2020 16:10:19
	System	27 Dec 2020 16:10:19

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-03T00:10:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4ad89d6b-7f4b-4176-8eb1-7f8342b14ec7'	System	03 Jan 2021 05:11:17
User entered 'No (N)'	System	03 Jan 2021 05:11:17

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-03T00:11:07', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4ad89d6b-7f4b-4176-8eb1-7f8342b14ec7'	System	03 Jan 2021 05:11:17
User entered 'No (N)'	System	03 Jan 2021 05:11:17

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-03T00:11:12', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4ad89d6b-7f4b-4176-8eb1-7f8342b14ec7' User entered '03 Jan 2021 00:11:12'	System	03 Jan 2021 05:11:17
	System	03 Jan 2021 05:11:17

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-10T13:17:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '13b81482-9a5b-49d4-b9fb-062433619125'	System	10 Jan 2021 18:17:22
User entered 'No (N)'	System	10 Jan 2021 18:17:22

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-10T13:17:14', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '13b81482-9a5b-49d4-b9fb-062433619125'	System	10 Jan 2021 18:17:22
User entered 'No (N)'	System	10 Jan 2021 18:17:22

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-10T13:17:20', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '13b81482-9a5b-49d4-b9fb-062433619125' User entered '10 Jan 2021 13:17:20'	System	10 Jan 2021 18:17:22
	System	10 Jan 2021 18:17:22

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-17T00:01:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '5477ac4e-0bba-4ef3-a31f-448ea4b242dd' User entered 'No (N)'	System	17 Jan 2021 05:02:17
	System	17 Jan 2021 05:02:17

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-17T00:01:50', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '5477ac4e-0bba-4ef3-a31f-448ea4b242dd' User entered 'No (N)'	System	17 Jan 2021 05:02:17

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-17T00:01:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '5477ac4e-0bba-4ef3-a31f-448ea4b242dd' User entered '17 Jan 2021 00:01:57'	System	17 Jan 2021 05:02:17
	System	17 Jan 2021 05:02:17

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-24T12:32:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '2e02b717-8398-4e8d-8d6f-99aacc20c665'	System	24 Jan 2021 17:32:19
User entered 'No (N)'	System	24 Jan 2021 17:32:19

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-24T12:32:10', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '2e02b717-8398-4e8d-8d6f-99aacc20c665'	System	24 Jan 2021 17:32:19
User entered 'No (N)'	System	24 Jan 2021 17:32:19

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-24T12:32:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '2e02b717-8398-4e8d-8d6f-99aacc20c665'	System	24 Jan 2021 17:32:19
User entered '24 Jan 2021 12:32:17'	System	24 Jan 2021 17:32:19

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-31T14:10:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e8321240-eefa-4cfc-ae74-dc0dc169527c' User entered 'No (N)'	System	31 Jan 2021 19:11:26
	System	31 Jan 2021 19:11:26

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-31T14:10:14', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e8321240-eefa-4cfc-ae74-dc0dc169527c' User entered 'No (N)'	System	31 Jan 2021 19:11:26

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-01-31T14:10:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e8321240-eefa-4cfc-ae74-dc0dc169527c' User entered '31 Jan 2021 14:10:22'	System	31 Jan 2021 19:11:26
	System	31 Jan 2021 19:11:26

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-10T22:28:27', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '66fd5e6d-a67c-4f96-b00c-d173ff11a728'	System	11 Feb 2021 03:28:39
User entered 'No (N)'	System	11 Feb 2021 03:28:39

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-10T22:28:31', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '66fd5e6d-a67c-4f96-b00c-d173ff11a728'	System	11 Feb 2021 03:28:39
User entered 'No (N)'	System	11 Feb 2021 03:28:39

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-10T22:28:36', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '66fd5e6d-a67c-4f96-b00c-d173ff11a728' User entered '10 Feb 2021 22:28:36'	System	11 Feb 2021 03:28:39
	System	11 Feb 2021 03:28:39

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-14T08:50:42', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '341dccc3-9e0e-4e1d-945d-9d57de59fefa' User entered 'No (N)'	System	16 Feb 2021 06:48:11
	System	16 Feb 2021 06:48:11

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-14T08:50:47', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '341dccc3-9e0e-4e1d-945d-9d57de59fefa' User entered 'No (N)'	System	16 Feb 2021 06:48:11

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-14T08:50:54', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '341dccc3-9e0e-4e1d-945d-9d57de59fefa' User entered '14 Feb 2021 08:50:54'	System	16 Feb 2021 06:48:11
	System	16 Feb 2021 06:48:11

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-21T00:49:11', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7ad1ab9a-be96-434a-80e8-eaf6d896590e' User entered 'No (N)'	System	21 Feb 2021 05:49:24
	System	21 Feb 2021 05:49:24

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-21T00:49:16', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7ad1ab9a-be96-434a-80e8-eaf6d896590e' User entered 'No (N)'	System	21 Feb 2021 05:49:24

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-02-21T00:49:21', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7ad1ab9a-be96-434a-80e8-eaf6d896590e' User entered '21 Feb 2021 00:49:21'	System	21 Feb 2021 05:49:24
	System	21 Feb 2021 05:49:24

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-02T19:28:39-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a124b6ea-2ecf-4807-926c-41836e3c4799'	System	03 Mar 2021 00:28:52
User entered 'No (N)'	System	03 Mar 2021 00:28:52

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-02T19:28:45-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a124b6ea-2ecf-4807-926c-41836e3c4799'	System	03 Mar 2021 00:28:52
User entered 'No (N)'	System	03 Mar 2021 00:28:52

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-02T19:28:49-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a124b6ea-2ecf-4807-926c-41836e3c4799'	System	03 Mar 2021 00:28:52
User entered '02 Mar 2021 19:28:49'	System	03 Mar 2021 00:28:52

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-07T03:50:29-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ea94a54f-f201-4425-b7c9-1c454162684e' User entered 'No (N)'	System	07 Mar 2021 08:51:58
	System	07 Mar 2021 08:51:58

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-07T03:50:37-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ea94a54f-f201-4425-b7c9-1c454162684e'	System	07 Mar 2021 08:51:58
User entered 'No (N)'	System	07 Mar 2021 08:51:58

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-07T03:51:54-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ea94a54f-f201-4425-b7c9-1c454162684e' User entered '07 Mar 2021 03:51:54'	System	07 Mar 2021 08:51:58
	System	07 Mar 2021 08:51:58

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-14T00:02:39-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a3992330-c259-4a94-b9ad-b168d95ca80f' User entered 'No (N)'	System	14 Mar 2021 05:07:02
	System	14 Mar 2021 05:07:02

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-14T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a3992330-c259-4a94-b9ad-b168d95ca80f' User entered 'No (N)'	System	14 Mar 2021 05:07:02
	System	14 Mar 2021 05:07:02

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-14T00:02:53-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a3992330-c259-4a94-b9ad-b168d95ca80f' User entered '14 Mar 2021 00:02:53'	System	14 Mar 2021 05:07:02
	System	14 Mar 2021 05:07:02

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-21T19:35:04-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '518df9f5-b19e-4eef-943d-18ff4edb2c5f'	System	21 Mar 2021 23:35:15
User entered 'No (N)'	System	21 Mar 2021 23:35:15

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-21T19:35:09-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '518df9f5-b19e-4eef-943d-18ff4edb2c5f'	System	21 Mar 2021 23:35:15
User entered 'No (N)'	System	21 Mar 2021 23:35:15

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-21T19:35:13-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '518df9f5-b19e-4eef-943d-18ff4edb2c5f' User entered '21 Mar 2021 19:35:13'	System	21 Mar 2021 23:35:15
	System	21 Mar 2021 23:35:15

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-29T12:42:03-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '31de8a09-e771-4d4a-9749-d57179b07f89'	System	29 Mar 2021 16:42:35
User entered 'No (N)'	System	29 Mar 2021 16:42:35

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-29T12:42:16-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '31de8a09-e771-4d4a-9749-d57179b07f89'	System	29 Mar 2021 16:42:35
User entered 'No (N)'	System	29 Mar 2021 16:42:35

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-29T12:42:23-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '31de8a09-e771-4d4a-9749-d57179b07f89' User entered '29 Mar 2021 12:42:23'	System	29 Mar 2021 16:42:35
	System	29 Mar 2021 16:42:35

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-06T12:16:58-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '717ddd9a-2a42-4db0-bf06-0a9b0297f381' User entered 'No (N)'	System	06 Apr 2021 16:18:41
	System	06 Apr 2021 16:18:41

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-06T12:17:04-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '717ddd9a-2a42-4db0-bf06-0a9b0297f381'	System	06 Apr 2021 16:18:41
User entered 'No (N)'	System	06 Apr 2021 16:18:41

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-06T12:17:11-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '717ddd9a-2a42-4db0-bf06-0a9b0297f381'	System	06 Apr 2021 16:18:41
User entered '06 Apr 2021 12:17:11'	System	06 Apr 2021 16:18:41

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-11T07:15:30-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'b8a66c62-b56f-401c-8386-7d4aeca6b8e0'	System	11 Apr 2021 11:15:50
User entered 'No (N)'	System	11 Apr 2021 11:15:50

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-11T07:15:41-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'b8a66c62-b56f-401c-8386-7d4aeca6b8e0'	System	11 Apr 2021 11:15:50
User entered 'No (N)'	System	11 Apr 2021 11:15:50

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-11T07:15:48-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'b8a66c62-b56f-401c-8386-7d4aeca6b8e0' User entered '11 Apr 2021 07:15:48'	System	11 Apr 2021 11:15:50
	System	11 Apr 2021 11:15:50

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-22T12:05:52-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4ddd408d-391b-48b5-8a21-8760c591535c'	System	22 Apr 2021 16:09:39
User entered 'No (N)'	System	22 Apr 2021 16:09:39

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-22T12:05:59-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4ddd408d-391b-48b5-8a21-8760c591535c'	System	22 Apr 2021 16:09:39
User entered 'No (N)'	System	22 Apr 2021 16:09:39

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-22T12:06:04-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4ddd408d-391b-48b5-8a21-8760c591535c'	System	22 Apr 2021 16:09:39
User entered '22 Apr 2021 12:06:04'	System	22 Apr 2021 16:09:39

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-28T11:31:31-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '9ff088bc-372f-4dbf-8065-3d98c00da19b'	System	28 Apr 2021 22:41:11
User entered 'No (N)'	System	28 Apr 2021 22:41:11

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-28T11:31:58-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '9ff088bc-372f-4dbf-8065-3d98c00da19b'	System	28 Apr 2021 22:41:11
User entered 'No (N)'	System	28 Apr 2021 22:41:11

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-04-28T11:32:04-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '9ff088bc-372f-4dbf-8065-3d98c00da19b'	System	28 Apr 2021 22:41:11
User entered '28 Apr 2021 11:32:04'	System	28 Apr 2021 22:41:11

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-05-03T05:59:10-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '69bcaed2-7ee5-4104-9040-6e03327f89aa'	System	03 May 2021 09:59:31
User entered 'No (N)'	System	03 May 2021 09:59:31

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-05-03T05:59:18-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '69bcaed2-7ee5-4104-9040-6e03327f89aa'	System	03 May 2021 09:59:31
User entered 'No (N)'	System	03 May 2021 09:59:31

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-05-03T05:59:28-04:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '69bcaed2-7ee5-4104-9040-6e03327f89aa' User entered '03 May 2021 05:59:28'	System	03 May 2021 09:59:31
	System	03 May 2021 09:59:31

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:50:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:50:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-02T19:29:15-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '77410f38-31fa-4fe5-b8fd-6ee1a8d805e6'	System	03 Mar 2021 00:30:13
User entered 'Yes (Y)'	System	03 Mar 2021 00:30:13

US3482284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:50:35

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)	30 Apr 2021 18:36:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-02T19:29:56-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '77410f38-31fa-4fe5-b8fd-6ee1a8d805e6'	System	03 Mar 2021 00:30:13
User entered 'No (N)'	System	03 Mar 2021 00:30:13

US3482284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:50:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:36:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6E6E6C5E-CF19-4463-8074-7F0454AD59BF)', Time: '2021-03-02T19:30:03-05:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '77410f38-31fa-4fe5-b8fd-6ee1a8d805e6' User entered '02 Mar 2021 19:30:03'	System	03 Mar 2021 00:30:13
	System	03 Mar 2021 00:30:13

US3482284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:43:20

US3482284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:43:20

US3482284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:43:20

US3482284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:43:20

US3482284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 22:43:26

US3482284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:20:25
User entered 'I'	System	08 Jan 2021 22:43:26

US3482284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:16

US3482284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:16

US3482284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:16

US3482284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:16

US3482284

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:21

US3482284

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User entered 'I'	System	09 Feb 2021 20:50:21

US3482284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:15:56

US3482284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:15:56

US3482284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:15:56

US3482284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:15:56

US3482284

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:16:03

US3482284

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:49:12
User entered 'I'	System	12 Mar 2021 17:16:03

US3482284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:48:26

US3482284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:19
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:48:26

US3482284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:48:26

US3482284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:19
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:48:26

US3482284

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:20:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:48:33

US3482284

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:48:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:50:35

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:07
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '12 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:50:35

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:07
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16:00'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:50:35

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:07
User entered '12 Nov 2020 16:00'	System	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:50:35

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:07
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Safety Call (Safety Call)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:50:35

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:07
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 17 (Day 17)' reason for change:	(b) (4)	
Data Entry Error	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12
User entered empty.	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '98'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '97.6' F	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 1 (Day 1)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '28 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 2 (Day 2)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 3 (Day 3)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '30 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	20 Nov 2020 15:42:05

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Severe (Severe)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 4 (Day 4)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '31 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 5 (Day 5)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '01 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 6 (Day 6)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '02 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 7 (Day 7)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '03 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 8 (Day 8)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '04 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 9 (Day 9)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '05 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 10 (Day 10)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '6 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 11 (Day 11)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '7 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 12 (Day 12)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '8 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 13 (Day 13)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '9 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 14 (Day 14)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '10 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 15 (Day 15)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '11 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 16 (Day 16)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '12 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Done (Not Done)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 18 (Day 18)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '14 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '93'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '96.8' F	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 19 (Day 19)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '99'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '97.7' F	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Day 20 (Day 20)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '96'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User entered '%'	System	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '97.6' F	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:50:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:58:18
User entered 'No (N)' reason for change: New Information	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:59
Query 'Data is required. Please complete.' answered with 'TEST PENDING' (Site from System).	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:38
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:48:28
User entered empty.	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:50:35

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:27
User entered '0'	System	19 Nov 2020 17:39:59

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:50:35

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:08:34
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:46:12

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:50:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:50:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '15 Nov 2020'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:50:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:50:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:50:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:50:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:50:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:50:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:50:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:50:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:50:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:50:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:50:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:50:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[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 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Clinic (Clinic)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User entered 'SICKD1'	System	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '10:34'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User entered '13 Nov 2020 10:34'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51
DataPoint set to visible.	System	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51
DataPoint set to visible.	System	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '97.6' F	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (Oral)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '89'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User entered 'bpm'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '26'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User entered 'breaths/min'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '134'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User entered 'mmHg'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '98'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User entered 'mmHg'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52

US3482284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:58

US3482284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:43:58

US3482284

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:50:35

[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 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:44:05

US3482284

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:50:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:16:52
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	13 Nov 2020 20:44:05

US3482284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:08:33

US3482284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:08:33

US3482284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Clinic (Clinic)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:08:33

US3482284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 23:08:33

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:28:59

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:24:53
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'subject only received one dose of mRNA (was not originally eligible for second dose) no option to enter "na" for "actual dose 2"' (Site from System).	Hollie Macenczak (b) (4)	15 Jan 2021 23:09:42
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	15 Jan 2021 23:08:58
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:28:59

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 09:55:20
User entered 'mRNA-1273 (mRNA-1273)'	Hollie Macenczak (b) (4)	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	22 Jan 2021 21:15:29
User entered empty.	Hollie Macenczak (b) (4)	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	15 Jan 2021 23:08:58

US3482284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:50:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'I'	System	22 Jan 2021 21:15:29
User entered empty.	System	15 Jan 2021 23:08:58

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	02 Feb 2021 22:13:20
DataPoint set to visible.	System	22 Jan 2021 21:15:29

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	02 Feb 2021 22:13:20
DataPoint set to visible.	System	22 Jan 2021 21:15:29

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User accepted default value 'Pre-Dose (PREDOSE)'	Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '12:40'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '15 Jan 2021 12:40'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '97.9' F	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (Oral)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '75'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'bpm'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '18'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'breaths/min'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '128'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'mmHg'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '89'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'mmHg'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:50:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered empty.	System	02 Feb 2021 22:13:20
DataPoint set to visible.	System	22 Jan 2021 21:15:29

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User accepted default value 'Post-Dose (POSTDOSE)'	Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Feb 2021 22:13:39
User entered '15 Jan 2021' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	02 Feb 2021 22:13:39
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Feb 2021 22:13:20
User entered empty.	Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	02 Feb 2021 22:13:39
data change (Site from System).		02 Feb 2021 22:13:39
User entered '14:39' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	02 Feb 2021 22:13:39
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Feb 2021 22:13:20
User entered empty.	Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '15 Jan 2021 14:39'	System	02 Feb 2021 22:13:39
User entered empty.	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '98.1' F	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (Oral)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '79'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'bpm'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '24'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'breaths/min'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '129'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'mmHg'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '88'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:20

US3482284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:50:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'mmHg'	System	02 Feb 2021 22:13:20

US3482284

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:47

US3482284

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:13:47

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'mRNA-1273'	System	02 Feb 2021 22:14:22
DataPoint set to visible.	System	22 Jan 2021 21:15:29

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13:53'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '15 Jan 2021 13:53'	System	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'ONCE'	System	02 Feb 2021 22:14:22

US3482284

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

Form: Exposure

Generated On: 09 Jun 2021 17:50:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 22:14:22

US3482284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:12:01

US3482284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:12:01

US3482284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13:05'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:12:01

US3482284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '15 Jan 2021 13:05'	System	15 Jan 2021 23:12:01

US3482284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:12:16

US3482284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:50:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '15 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:12:16

US3482284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '13:08'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 23:12:16

US3482284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:50:35

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered '15 Jan 2021 13:08'	System	15 Jan 2021 23:12:16

US3482284

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

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Jan 2021 21:15:46

US3482284

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

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:04
User entered 'I'	System	22 Jan 2021 21:15:46

US3482284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Jan 2021 21:16:10

US3482284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '22 Jan 2021'	(b) (4) Hollie Macenczak (b) (4)	22 Jan 2021 21:16:10

US3482284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Hollie Macenczak (b) (4)	22 Jan 2021 21:16:10

US3482284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:50:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	22 Jan 2021 21:16:10

US3482284

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	22 Jan 2021 21:16:15

US3482284

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:20
User entered 'I'	System	22 Jan 2021 21:16:15

US3482284

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:50:35

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:20
User entered '1'	System	22 Jan 2021 21:16:15
DataPoint set to visible.	System	22 Jan 2021 21:16:15

US3482284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	(b) (4)	
	System	12 Feb 2021 23:38:55
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	12 Feb 2021 23:38:42
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	12 Feb 2021 23:38:42

US3482284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Hollie Macenczak (b) (4)	12 Feb 2021 23:38:55
User entered empty.		
	Hollie Macenczak (b) (4)	12 Feb 2021 23:38:42

US3482284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Clinic (Clinic)'	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:38:42

US3482284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:50:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User entered 'OLD29'	System	12 Feb 2021 23:38:42

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User entered empty.	System	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User entered empty.	System	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User entered empty.	System	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User entered empty.	System	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User entered empty.	System	12 Feb 2021 23:40:14

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01

US3482284

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:50:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01

US3482284

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:18

US3482284

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:50:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:18

US3482284

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:38

US3482284

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '12:55'	(b) (4) Hollie Macenczak (b) (4)	12 Feb 2021 23:40:38

US3482284

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:50:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:14:01
User entered '12 Feb 2021 12:55'	System	12 Feb 2021 23:40:38

US3482284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:50:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:35:11

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 13:15:37
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered	System	02 Nov 2020 21:18:05
'USA-US106-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	02 Nov 2020 21:18:05

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:54
Data point term sent to Coder	System	30 Oct 2020 20:37:45
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:33:56
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:56:55
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:53:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
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)	11 Nov 2020 13:38:38
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 provided' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:09:44
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:53:30
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 20:53:30
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:53:30
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:52:36
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)	09 Nov 2020 18:59:01
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:33:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:41:22
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:07:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
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) (4), (b) (6)	19 Nov 2020 12:26:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
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 has not been discharged yet, Medical records have been requested' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 21:04:07
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	30 Oct 2020 20:37:10
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:56:55
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '31 Oct 2020' reason for change: New Information	Michele McCullough (b) (4)	06 Nov 2020 15:36:36
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)' reason for change: New Information	Michele McCullough (b) (4)	06 Nov 2020 15:36:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1' reason for change: New Information	Michele McCullough	06 Nov 2020 15:36:36
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:41:29
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:07:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:49:45
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:07:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 13:38:45
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'no action has been taken at this time.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:10:09
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:01:13
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
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)	11 Nov 2020 13:38:51
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 'outcome is entered' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:10:40
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:52:36
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)	09 Nov 2020 18:59:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	10 Nov 2020 21:56:55
User entered 'SHORTNESS OF BREATH & IMPAIRED CARDIAC FUNCTION (CHF)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Nov 2020 21:56:55
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:52:36
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:47:15
User closed query 'Per CDM re-query: Response noted; Please review if dose can be retrieved for "INTEGRILIN DRIP" from the subject as the subject is still in the study and record the details in Con med eCRF. If the dose can not be retrieved record dose with 'UNK' and enter all other details in con med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:09:35
User closed query 'Per CDM re-query: Response noted; However please review and add the Con procedure performed which showed the result of 'ELEVATED TROPONIN'. Please update as appropriate else clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:09:00
Query 'Per CDM re-query: Response noted; However please review and add the Con procedure performed which showed the result of 'ELEVATED TROPONIN'. Please update as appropriate else clarify in query response. ' answered with 'con procedure updated' (Site from DM).	Hollie Macenczak (b) (4)	02 Feb 2021 22:15:58
Query 'Per CDM re-query: Response noted; Please review if dose can be retrieved for "INTEGRILIN DRIP" from the subject as the subject is still in the study and record the details in Con med eCRF. If the dose can not be retrieved record dose with 'UNK' and enter all other details in con med eCRF as appropriate. ' answered with 'integrilin added to con med list' (Site from DM).	Hollie Macenczak (b) (4)	02 Feb 2021 20:58:58
User closed query 'Per DM CLR: SAE Narrative = LABS SHOWED ELEVATED TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:58:40

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Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Response noted; However please review and add the Con procedure performed which showed the result of 'ELEVATED TROPONIN'. Please update as appropriate else clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:58:38
User closed query 'Per DM CLR: SAE Narrative = WAS TREATED WITH INTEGRILIN DRIP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:54:22
User opened query 'Per CDM re-query: Response noted; Please review if dose can be retrieved for "INTEGRILIN DRIP" from the subject as the subject is still in the study and record the details in Con med eCRF. If the dose can not be retrieved record dose with 'UNK' and enter all other details in con med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:54:16
User closed query 'Per DM CLR: SAE Narrative = MORPHINE FOR PAIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:48:22
User closed query 'Per CDM Requery: Response noted, however baseline renal impairment is not recorded in the medical history eCRF. Please verify and update data accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:47:18
User closed query 'Per DM CLR: SAE Narrative = EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:45:09
Query 'Per DM CLR: SAE Narrative = MORPHINE FOR PAIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Medical records reviewed. Morphine was listed in the ER narrative as ordered "as needed" but there is no record of administration. Removed this language from SAE narrative.' (Site from DM).	Hollie Macenczak (b) (4)	29 Jan 2021 19:38:29
DataPoint Un-verified.	Hollie Macenczak (b) (4)	29 Jan 2021 19:35:14

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WITH CHEST PAIN BEGINNING 28OCT2020. INITIALLY THOUGHT IT WAS INDIGESTION DUE TO DINNER FROM PREVIOUS NIGHT. IT PERSISTED TO 29OCT2020, AND PT STARTED HAVING DIZZINESS AND SHORTNESS OF BREATH WITH CLIMBING A LADDER FOR WORK, SO SUBJECT WENT TO ED. EKG REVEALED ST ELEVATION MI AND LABS SHOWED ELEVATED TROPONIN (MAX 45.5). WAS TREATED WITH NTG, ASAS, AND HEPARIN IV. SUBJECT UNDERWENT EMERGENT CARDIAC CATHETERIZATION WITH UNSUCCESSFUL THROMBECTOMY & ANGIOPLASTY TO TOTALLY OCCLUDED MID RCA. HE WAS TRANSFERRED TO ICU FOR ONGOING CARE. WAS TREATED WITH INTEGRILIN DRIP with CONTINUED BASELINE STATINS, BETA BLOCKER, AND AMLODIPINE. WAS NOTED TO HAVE RENAL IMPAIRMENT ON ADMISSION LABS. COVID PCR WAS NEGATIVE.PARTICIPANT IMPROVED DURING ADMISSION AND WAS D/C'D TO RETURN TO ATLANTA FOR F/U WITH REGULAR CARDIOLOGIST FOR FURTHER MANAGEMENT.' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	29 Jan 2021 19:35:14
Query 'Per DM CLR: SAE Narrative = EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Electrocardiogram added to con procedure list with a date of 10/29/2020.' (Site from DM).	Hollie Macenczak (b) (4)	29 Jan 2021 19:30:10
Query 'Per CDM Requery: Response noted, however baseline renal impairment is not recorded in the medical history eCRF. Please verify and update data accordingly.' answered with 'Chronic renal failure added on 17-nov-2020 #9 on medical history list' (Site from DM).	Hollie Macenczak (b) (4)	29 Jan 2021 19:23:18

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Requery: Response noted, however baseline renal impairment is not recorded in the medical history eCRF. Please verify and update data accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:34:08
User closed query 'Per DM CLR: SAE Narrative = WAS NOTED TO HAVE RENAL IMPAIRMENT ON ADMISSION LABS. However, please review and verify if RENAL IMPAIRMENT should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:34:08
Query 'Per DM CLR: SAE Narrative = WAS NOTED TO HAVE RENAL IMPAIRMENT ON ADMISSION LABS. However, please review and verify if RENAL IMPAIRMENT should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'HAS BASELINE RENAL IMPAIRMENT -- SEE MEDICAL HISTORY. UNCLEAR IF THIS IS AN EXACERBATION AS TREATING HOSPITAL WAS NOT FAMILIAR WITH HIS MEDICAL HISTORY.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:17:20
Query 'Per DM CLR: SAE Narrative = LABS SHOWED ELEVATED TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'LABS NOT RECORDED AS CON PROCEDURE. SEE SCANNED MEDICAL RECORD SENT TO iqvia.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:16:25
Query 'Per DM CLR: SAE Narrative = WAS TREATED WITH INTEGRILIN DRIP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UNABLE TO FIND DOSE IN MEDICAL RECORD, BUT THERE WAS REFERENCE TO IT IN NARRATIVE OF CHART. SEE SCANNED MEDICAL RECORD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:15:56

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = WAS NOTED TO HAVE RENAL IMPAIRMENT ON ADMISSION LABS. However, please review and verify if RENAL IMPAIRMENT should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 01:51:58
User opened query 'Per DM CLR: SAE Narrative = MORPHINE FOR PAIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 01:51:49
User opened query 'Per DM CLR: SAE Narrative = WAS TREATED WITH INTEGRILIN DRIP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 01:51:39
User opened query 'Per DM CLR: SAE Narrative = LABS SHOWED ELEVATED TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 01:51:25
User opened query 'Per DM CLR: SAE Narrative = EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 01:51:00
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 12:24:43
User closed query 'PV Query: Please clarify whether the event of acute on chronic systolic heart failure refers to the sequela of the event of myocardial infarction which is described as Impaired cardiac function (CHF).' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 14:30:47

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify whether the event of acute on chronic systolic heart failure refers to the sequela of the event of myocardial infarction which is described as Impaired cardiac function (CHF).' answered with 'acute on chronic systolic heart failure was a new diagnosis that described the sequellae of the STEMI and exacerbation of the sequellae' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:24:17
User opened query 'PV Query: Please clarify whether the event of acute on chronic systolic heart failure refers to the sequela of the event of myocardial infarction which is described as Impaired cardiac function (CHF).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:09:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 13:39:12
User closed query 'PV Query: Please provide the symptoms on the start date of the event.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 13:39:07
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)	11 Nov 2020 13:39:02
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)	11 Nov 2020 13:38:57

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[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 'DETAILS OF MEDS AND INTERVENTIONS IN NARRATIVE AS LISTED AND CON MEDS UPDATED IN DCF AND eCRF' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:53:48
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 'AWAITING CONFIRMATION OF TEST PERFORMED. VERBAL REPORT OF NEGATIVE TEST BY SUBJECT BUT NO RESULT SEEN IN ADMISSION RECORDS OR DISCHARGE SUMMARY.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:40:30
Query 'PV Query: Please provide the symptoms on the start date of the event.' answered with 'HEARTBURN AND SHORTNESS OF BREATH' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:39:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WITH CHEST PAIN BEGINNING 28OCT2020. INITIALLY THOUGHT IT WAS INDIGESTION DUE TO DINNER FROM PREVIOUS NIGHT. IT PERSISTED TO 29OCT2020, AND PT STARTED HAVING DIZZINESS AND SHORTNESS OF BREATH WITH CLIMBING A LADDER FOR WORK, SO SUBJECT WENT TO ED. EKG REVEALED ST ELEVATION Mi AND LABS SHOWED ELEVATED TROPONIN (MAX 45.5). WAS TREATED WITH NTG, ASAS, AND HEPARIN IV. SUBJECT UNDERWENT EMERGENT CARDIAC CATHETERIZATION WITH UNSUCCESSFUL THROMBECTOMY & ANGIOPLASTY TO TOTALLY OCCLUDED MID RCA. HE WAS TRANSFERRED TO ICU FOR ONGOING CARE. WAS TREATED WITH INTEGRILIN DRIP, MORPHINE FOR PAIN, AND CONTINUED BASELINE STATINS, BETA BLOCKER, AND AMLODIPINE. WAS NOTED TO HAVE RENAL IMPAIRMENT ON ADMISSION LABS. COVID PCR WAS NEGATIVE.PARTICIPANT IMPROVED DURING ADMISSION AND WAS D/C'D TO RETURN TO ATLANTA FOR F/U WITH REGULAR CARDIOLOGIST FOR FURTHER MANAGEMENT.' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:33:56
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records have been sent.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:13:41

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTICED CHEST PAIN BEGINNING 28OCT2020. IT PERSISTED INTO 29OCT2020 SO SUBJECT WENT TO ED WHERE EKG REVEALED ST ELEVATION. SUBJECT UNDERWENT CARDIAC CATHETERIZATION WITH UNSUCCESSFUL PCI TO TOTALLY OCCLUDED MID RCA. He was transferred to ICU for ongoing care. Was prescribed Integrillin drip for residual chest pain and pressure. Prescribed morphine for pain SUBJECT TO FOLLOW UP WITH CARDIOLOGIST. COVID PCR was negative.'	(b) (4), (b) (6)	10 Nov 2020 19:53:53
reason for change: New Information		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:01:47
User opened query 'PV Query: Please provide the symptoms on the start date of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:01:28
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)	09 Nov 2020 19:00:42
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)	09 Nov 2020 19:00:26
User entered 'Subject noticed chest pain beginning 28OCT2020. It persisted into 29OCT2020 so subject went to ED where EKG revealed ST elevation. Subject underwent cardiac catheterization with unsuccessful PCI to totally occluded mid RCA. Subject to follow up with cardiologist.' reason for change: New Information	Michele McCullough (b) (4)	06 Nov 2020 15:36:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'Awaiting medical records for further clarification' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 21:05:42
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:37:10
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 15:36:36
User entered '0'	System	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:40:47
User entered 'USA-US106-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	11 Nov 2020 13:40:41

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR: Please confirm the AE term "SHORTNESS OF BREATH, WORSENING", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM). Query 'Per DM CLR: Please confirm the AE term "SHORTNESS OF BREATH, WORSENING", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with "worsening" was added per prior query request/resolution' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:39:40
User opened query 'Per DM CLR: Please confirm the AE term "SHORTNESS OF BREATH, WORSENING", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	Hollie Macenczak (b) (4)	02 Mar 2021 18:32:09
User opened query 'Per DM CLR: Please confirm the AE term "SHORTNESS OF BREATH, WORSENING", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:38:50
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:50:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Increased shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 18:48:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 18:48:50
Data point term sent to Coder	System	22 Jan 2021 19:18:23
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 19:18:01
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 19:18:01

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'SHORTNESS OF BREATH, WORSENING' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Jan 2021 19:18:01
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:54:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:08:39
Data point term sent to Coder	System	11 Nov 2020 22:08:16
User entered 'SHORTNESS OF BREATH' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:07:40
Data point term sent to Coder	System	11 Nov 2020 21:56:56
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:55:59
Coding entries removed.	(b) (4), (b) (6)	11 Nov 2020 21:55:59
User entered 'SHORTNESS FO BREATH' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 21:55:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Chronic left ventricular failure, LLT: Chronic systolic heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:17:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:17:41
Data point term sent to Coder	System	10 Nov 2020 21:36:09
User entered 'SHORTNESS FO BREATH DUE TO ACUTE EXACERBATION OF CHRONIC SYSTOLIC HEART FAILURE'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '28 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
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' canceled (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:23:34
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:42:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:50:07
DataPoint Un-verified.	Hollie Macenczak (b) (4)	22 Dec 2020 22:19:53
User entered 'No (N)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 22:19:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:50:08
DataPoint Un-verified.	Hollie Macenczak (b) (4)	22 Dec 2020 22:19:53
User entered '20 Dec 2020' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 22:19:53
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)	18 Nov 2020 21:02:21
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 'Participant is again hospitalized for further exacerbation -- should we await disposition and discharge before answering query?' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:46:57
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)	16 Nov 2020 18:00:18
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:48:51
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)	25 Nov 2020 16:54:06
User entered empty.	System	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:35:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:35:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:35:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:35:18
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '5 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '7 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per CDM re-query: Response noted; Please review if AE term and indication in con med kept same for reconciliation of data. Please review and update as appropriate else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 11:16:39
Query 'Per CDM re-query: Response noted; Please review if AE term and indication in con med kept same for reconciliation of data. Please review and update as appropriate else please clarify.' answered with 'con meds #18, 21, 25 updated to reflect "SHORTNESS OF BREATH, WORSENING"' (Site from DM).	Hollie Macenczak (b) (4)	02 Feb 2021 20:43:20
User opened query 'Per CDM re-query: Response noted; Please review if AE term and indication in con med kept same for reconciliation of data. Please review and update as appropriate else please clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:36:18
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:29:07
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'SHORTNESS OF BREATH WAS ULTIMATELY FOUND TO BE RELATED TO CHF. MULTIPLE MEDS GIVEN FOR PRESUMPTIVE PNEUMONIA, ETC. SEE CON MEDS SECTION AND SCANNED MEDICAL RECORD THAT WAS FAXED TO IQVIA' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:11:37

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Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 01:54:08
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:56:51
Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' answered with 'Entered per IQVIA request I directive on SAE documentation in the eCRF. Discussed with RSM today and confirmed that diagnostic procedure info needs to be entered in RAVE for any SAE.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:56:10
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:39:26
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:29:15

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'PROCEDURES RECORDED. SEE SCANNED MEDICAL RECORD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:11:57
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 01:54:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
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) (4), (b) (6)	01 Feb 2021 15:49:07
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 end date to 20DEC2020' (Site from Safety).	Hollie Macenczak (b) (4)	29 Jan 2021 19:39:27
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:11:53
DataPoint Un-verified.	Hollie Macenczak (b) (4)	22 Dec 2020 22:19:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 22:19:53
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)	25 Nov 2020 16:54:22
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)	18 Nov 2020 21:02:26
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Participant is again hospitalized for further exacerbation -- will update as info is available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:47:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:59:21
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'PV Query: As the SAE of shortness of breath occurred at the same time as the myocardial infarction, please assess if shortness of breath is a symptom of the myocardial infarction as the sequelae of myocardial infarction was denoted as shortness of breath. Please assess and remove shortness of breath as an SAE as applicable, if to remain as a separate SAE please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:51:40
Query 'PV Query: As the SAE of shortness of breath occurred at the same time as the myocardial infarction, please assess if shortness of breath is a symptom of the myocardial infarction as the sequelae of myocardial infarction was denoted as shortness of breath. Please assess and remove shortness of breath as an SAE as applicable, if to remain as a separate SAE please state so.' answered with 'THIS REMAINS AS SEPARATE AE BECAUSE WE USED IT AS REASON TO ASSESS AND RULE OUT COVID ON ILLNESS VISIT. ULTIMATELY HE WAS FOUND TO ALSO HAVE CHF AND AN ARRHYTHMIA, SO IT WAS A COMBINATION OF FACTORS CONTRIBUTING TO THE SHORTNESS OF BREATH, BUT THAT IS THE SYMPTOM THAT MANDATED THE ILLNESS VISIT AND WHICH WORSENERED TO PROMPT HIM TO RETURN TO THE HOSPITAL ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:14:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:12:22
User opened query 'PV Query: As the SAE of shortness of breath occurred at the same time as the myocardial infarction, please assess if shortness of breath is a symptom of the myocardial infarction as the sequelae of myocardial infarction was denoted as shortness of breath. Please assess and remove shortness of breath as an SAE as applicable, if to remain as a separate SAE please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:19:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTE ON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE PRIOR VISIT IN CLINIC AND HAD AN ILLNESS VISIT HERE 13 NOV 2020. Update: PARTICIPANT SEEN ON 4 DEC 2020 FOR DAY 29 VISIT; NO IP GIVEN. MEDICAL HX CLARIFIED AND UPDATED. STILL WAITING FOR RECORDS FROM 3RD HOSPITALIZATION. PT STILL WITH ONGOING TACHYPNEA (26 RESP AT REST) AND +1 Pitting LE EDEMA.' reason for change: New Information	(b) (4), (b) (6)	09 Dec 2020 00:10:19
User closed query 'PV Query: Please confirm the administration dates for Nitroglycerine concomitant medication, which are listed as prior to event onset as 20 Oct 2020. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:24:35

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTEON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE PRIOR VISIT IN CLINIC AND HAD AN ILLNESS VISIT HERE 13 NOV 2020.' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 19:51:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTEON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE LAST IN CLINIC AND HAD AN ILLNESS VISIT HERE 13 NOV 2020.' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 19:49:27

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. WE ARE AWAITING FULL HOSPITAL D/C RECORDS AT THIS TIME. PT CURRENTLY NOTES SOB AT REST, WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE LAST IN CLINIC AND HAD AN ILLNESS VISIT HERE 13 NOV 2020.' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 14:07:07
User opened query 'PV Query: Please confirm the administration dates for Nitroglycerine concomitant medication, which are listed as prior to event onset as 20 Oct 2020. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:55:01
User closed query 'PV Query: Please clarify the chronic status of the event of acute on chronic systolic heart failure. Did the subject have chronic (systolic) heart failure as medical history? If so, please list it in the medical history.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 14:31:10

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify the chronic status of the event of acute on chronic systolic heart failure. Did the subject have chronic (systolic) heart failure as medical history? If so, please list it in the medical history.' answered with 'The participant did not report a prior history of heart failure and does not even endorse that now as a diagnosis. He just reports that he had a clot in his heart. His long ter medical records are still being reviewed and received to gain additional reliable information.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:26:22
User opened query 'PV Query: Please clarify the chronic status of the event of acute on chronic systolic heart failure. Did the subject have chronic (systolic) heart failure as medical history? If so, please list it in the medical history.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:08:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. WE ARE AWAITING FULL HOSPITAL D/C RECORDS AT THIS TIME. PT CURRENTLY NOTES SOB AT REST, WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE LAST IN CLINIC AND WILL HAVE AN ILLNESS VISIT HERE 13 NOV 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:37:40

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS.'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:35:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 21:35:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:25:00
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:05:24
User entered	(b) (4), (b) (6)	12 Nov 2020 15:05:19
'USA-US106-2020-mRNA-1273-P301000002'		

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:27:26
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Acute left ventricular failure, LLT: Acute systolic heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:00:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:00:39
Data point term sent to Coder	System	11 Nov 2020 22:04:06
User entered 'ACUTE ON CHRONIC SYSTOLIC HEART FAILURE'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:27:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:37:26
User closed query 'The source notes this response as "no"; please review and update RDC.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 04:27:18
Query 'The source notes this response as "no"; please review and update RDC.' answered with 'response changed to "no"' (Site from CRA).	Hollie Macenczak (b) (4)	24 Nov 2020 21:03:49
User entered 'No (N)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	24 Nov 2020 20:58:31
User opened query 'The source notes this response as "no"; please review and update RDC.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:04:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
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' canceled (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:23:41
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:42:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:17
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:29:14
User entered '5 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:29:29
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:03:41

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:51:02
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Jan 2021 21:20:35
DataPoint Un-verified.	Hollie Macenczak (b) (4)	29 Jan 2021 21:20:35
User entered 'No (N)' reason for change: New Information	Hollie Macenczak (b) (4)	29 Jan 2021 21:20:35
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Jan 2021 21:20:06
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:51:00
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Jan 2021 21:20:06
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	29 Jan 2021 21:20:06
DataPoint Un-verified.	Hollie Macenczak (b) (4)	29 Jan 2021 21:20:06
User entered '4 Jan 2021' reason for change: New Information	Hollie Macenczak (b) (4)	29 Jan 2021 21:20:06
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	22 Jan 2021 19:04:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:47
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)	18 Nov 2020 21:00:40
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 'Participant again hospitalized 16 NOV for further exacerbation and is still admitted. Will update as further info is available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:49:09
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)	16 Nov 2020 18:00:50
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	24 Nov 2020 19:29:52
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:52:07
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)	25 Nov 2020 16:51:16
User entered empty.	System	11 Nov 2020 22:03:41

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Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:29:56
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:30:00
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:30:07
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:30:04
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Nov 2020 22:04:05
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	11 Nov 2020 22:04:05
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:04:05
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Nov 2020 22:03:41
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Form: Adverse Events (3)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:30:15
User entered '5 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query ' PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization 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) (4), (b) (6)	21 Jan 2021 18:05:46
Query ' PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization 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 'Updated medical records with discharge summary included e-mailed to safety_moderna@iqvia.com on 20-jan-2021' (Site from Safety).	Hollie Macenczak (b) (4)	20 Jan 2021 17:36:54
User opened query ' PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 19:40:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:17
User entered '7 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:30:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Form: Adverse Events (3)

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:30:22
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 22:04:05
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	11 Nov 2020 22:04:05
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 22:03:41
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:31:51
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:31:54
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:31:56
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:31:59
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:32:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:32:20
User closed query 'PV Query: Please confirm the action taken as it was reported as study drug withdrawn. As study drug was already withdrawn to earlier MI, please update to "not applicable" (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 14:34:00
Query 'PV Query: Please confirm the action taken as it was reported as study drug withdrawn. As study drug was already withdrawn to earlier MI, please update to "not applicable" answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:09:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:07:39
User opened query 'PV Query: Please confirm the action taken as it was reported as study drug withdrawn. As study drug was already withdrawn to earlier MI, please update to "not applicable" (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:05:25
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:32:43
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:06:24
Query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Lasix was given for the peripheral and pulmonary edema that resulted from the heart failure. Amiodarone is given for heart failure, as well as arrhythmia (another one of patients diagnoses). ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:58:32
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:40:31
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)	25 Jan 2021 16:51:54
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 'CON MEDS ENTERED. ALSO, SEE SCANNED MEDICAL RECORDS WHICH WERE FAXED TO IQVIA.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:03:13

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[Concomitant Medication](#)

Audit	User	Time (GMT)
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)	30 Dec 2020 19:40:16
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:44
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'Entered per IQVIA request I directive on SAE documentation in the eCRF. Discussed with RSM today and confirmed that diagnostic procedure info needs to be entered in RAVE for any SAE.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:06:27
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'Entered per IQVIA request I directive on SAE documentation in the eCRF. Discussed with RSM today and confirmed that diagnostic procedure info needs to be entered in RAVE for any SAE.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:56:38
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:39:57
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 09:50:57
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'ENTERED' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:08:46

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 01:54:56
	(b) (4), (b) (6)	24 Nov 2020 19:32:46
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:54:10
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)	25 Jan 2021 16:51:58
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 'ONGOING. NEW DIAGNOSIS OF CONGESTIVE HEART FAILURE. CURRENTLY IMPROVED, BUT THIS IS CHRONIC.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:05:14
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 19:04:38
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	(b) (4), (b) (6)	22 Jan 2021 19:04:38
Query 'Per source, this SAE has recovered. Please confirm and update.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 20:38:13
User opened query 'Per source, this SAE has recovered. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 20:06:06
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)	08 Dec 2020 19:37:45
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)	01 Dec 2020 13:16:07

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[Outcome](#)

Audit	User	Time (GMT)
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 'NOT RESOLVED; WITH SEQUELLAE/CHRONIC DECREASE IN CARDIAC FUNCTION RELATED TO MYOCARDIAL INJURY SUSTAINED DURING STEMI.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 22:15:12
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)	25 Nov 2020 16:51:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:53
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)	18 Nov 2020 21:00:54
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 'Participant rehospitalized 16 NOV for further exacerbation. Still admitted. Will update as info becomes available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:49:55
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)	16 Nov 2020 17:59:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:58:36
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	22 Jan 2021 19:06:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 19:06:19
User entered 'SEQUELA IS NEW DX OF CHF (CHRONIC). HAS INTERMITTENT EXACERBATIONS WITH EDEMA, ET AL.'	(b) (4), (b) (6)	22 Jan 2021 19:06:19
reason for change: Per Query Resolution		
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	22 Jan 2021 19:04:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:58
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:38:32
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTE ON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE PRIOR VISIT IN CLINIC AND HAD AN ILLNESS VISIT HERE 13 NOV 2020. SEE MEDICAL RECORDS FROM HOSPITALIZATION SENT FOR REVIEW. UPDATE: PARTICIPANT SEEN ON 4 DEC 2020 FOR DAY 29 VISIT; NO IP GIVEN. MEDICAL HX CLARIFIED AND UPDATED. STILL WAITING FOR RECORDS FROM 3RD HOSPITALIZATION. PT STILL WITH ONGOING TACHYPNEA (26 RESP AT REST) AND +1 PITTING LE EDEMA.' reason for change: New Information	(b) (4), (b) (6)	10 Dec 2020 23:05:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTEON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE PRIOR VISIT IN CLINIC AND HAD AN ILLNESS VISIT HERE 13 NOV 2020. SEE MEDICAL RECORDS FROM HOSPITALIZATION SENT FOR REVIEW. Update: PARTICIPANT SEEN ON 4 DEC 2020 FOR DAY 29 VISIT; NO IP GIVEN. MEDICAL HX CLARIFIED AND UPDATED. STILL WAITING FOR RECORDS FROM 3RD HOSPITALIZATION. PT STILL WITH ONGOING TACHYPNEA (26 RESP AT REST) AND +1 PITTING LE EDEMA.' reason for change: New Information	(b) (4), (b) (6)	09 Dec 2020 00:09:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:43:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
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)	02 Dec 2020 14:43:44

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[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 'PARTICIPANT WENT TO PCP FOR FOLLOW UP AND SOB. FOUND TO HAVE NEW ONSET ATRIAL FLUTTER AND HYPOXIA TO 90%. SENT TO ER. PRESENTED TO ER FOR SAME &. ADMITTED TO ICU WITH DX CHF EXACERBATION VS. PNEUMONIA. EMPIRIC ABX OF ROCEPHIN AND DOXYCYCLINE GIVEN. CXR SHOWED MULTIFOCAL OPACITIES AND ULTRASOUND OF LUNGS SHOWED PULMONARY EDEMA. SEVERE RIGHT VENTRICULAR FAILURE ON ECHOCARDIOGRAM WITH MARKED INCREASED MITRAL AND TRICUSPID REGURGITATION OVER BASELINE, WITHOUT EVIDENCE OF PERICARDIAL EFFUSION. CHA2DS2VASC=3. THOUGH PT SEEMED EUVOLEMIC, 1 DOSE LASIX 40MG IV GIVEN. TRANSITIONED FROM INITIAL HEPARIN PLUS ASA PLUS PLAVIX TO ASA & XARELTO 20MG PO DAILY FOR CLOT PROPHY. NEW ONSET ATRIAL FLUTTER WAS DX AS INCISIONAL VS CAVOTRICUSPID ISTHMUS DEPENDENT PER CARDIOLOGY AND TEE/DCCV PLANNED WITH ELECTROPHYSIOLOGY DEPARTMENT. PT DECLINED PROCEDURE AS INPATIENT AND IMPROVED ENOUGHT TO BE TRANSFERRED TO REGULAR CARDIAC FLOOR AFTER ICU OBSERVATION. PT LEFT AMA AFTER REFUSING ABLATION AND SCHEDULED TO FOLLOW UP OUTPATIENT WITH PERSONAL CARDIOLOGIST. METOPROLOL, ASA, STATIN CONTINUED. PLAVIX WAS TO BE DISCONTINUED AFTER STARTING XARELTO,	(b) (4), (b) (6)	01 Dec 2020 20:49:23

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
BUT PARTICIPANT LATER STATED HE WAS CONTINUING BOTH PER HIS PERSONAL CARDIOLOGIST. WILL UPDATE MEDS IN CON MEDS SECTION.' (Site from Safety).		
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB/DOE THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. RESTING PULSE OX WAS 90% ON ROOM AIR. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU. DX WITH ATRIAL FLUTTER AND NEW ONSET ACUTEON CHRONIC HEART FAILURE. TEE WITH ELECTROCONVERSION OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT LEFT AMA AND AWAITED FURTHER OUTPATIENT IMAGING AND EVALUATION WITH PERSONAL CARDIOLOGIST TO DECIDE NEXT STEPS. AT TIME OF THIS WRITING 2ND WEEK OF NOVEMBER, PT HAD DOE AND SOB AT REST, WORSE WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE PRIOR VISIT IN CLINIC AND HAD AN ILLNESS VISIT HERE 13 NOV 2020. SEE MEDICAL RECORDS FROM HOSPITALIZATION SENT FOR REVIEW.'	(b) (4), (b) (6)	01 Dec 2020 19:53:39
reason for change: Per Query Resolution		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No reference ranges provided, only abnormals. 5 NOV 2020: @ 1510: i-Stat POC troponin=3.49, BUN=24, Creatinine=1.66(H), K=3.9, Na=139, Mag=2.0, AST=85(H), ALT=192(H), GFR=51(L), GLU=86. WBC=17.6 (H), HGB=17.2, HCT=52.3(H), PLT=240, relative neutrophils=85.6(H), abs neutrophils=15.1(H), relative lymphs=7.6 (H), abs lymphs=1.3(H), abs monocytes= 1.0(H); all other CBC components WNL per note. PT=15.5(H), PTT=35.9(H), INR=1.23(H). D-dimer=2.55(H), BNP=1,009.0 (H). @ 1706: HGB=18.8(H), HCT=55(H); GLU=100. @ 1810: Troponin=5.390 (H), @ 2059: Troponin=4.54 (H). @ 2326: Na=138, K=3.6, BUN=24, Cr=1.61(H), Mag=1.6(L), GLU=103(H). COVID test= negative. Blood culture= pending (no final report received). ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 17:09:09
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. NO REPORT OF CHF IN PMHX PRIOR TO HEART ATTACK IN LATE OCTOBER.'	(b) (4), (b) (6)	01 Dec 2020 17:09:01
reason for change: Per Query Resolution		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary for the 18 Nov 2020 hospitalization 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)	01 Dec 2020 13:16:12
Query 'PV Query: Please send a hospital discharge summary for the 18 Nov 2020 hospitalization 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 'RECORDS FOR 18 NOV HOSPITALIZATION ARE RELATED TO SUBSEQUENT AE. ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 22:15:46
User opened query 'PV Query: Please send a hospital discharge summary for the 18 Nov 2020 hospitalization 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)	25 Nov 2020 16:53:07
User closed query 'PV Query: Please confirm that chronic kidney disease is included in medical history. If so, please list it in the medical history. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:02:02
User closed query 'PV Query: Please confirm if echocardiogram was performed. If so, please provide results.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:01:54
User closed query 'PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization 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)	18 Nov 2020 21:01:35
Query 'PV Query: Please confirm that chronic kidney disease is included in medical history. If so, please list it in the medical history. If not, please explain.' answered with 'ADDED.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:44:20

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if echocardiogram was performed. If so, please provide results.' answered with '5 NOV 2020 echo performed; reported: "LVEF severely depressed. Calculated EF=29%. Regional wall motion abnormalities noted. Dilated RV with with severe RV dysfunction. Moderate to severe mitral regurgitation. Moderate to severe tricuspid regurg. A prior echo was conducted 20 FEB 2020. Compared to prior study, LV EF is lower today (on 5 NOV). There is more mitral and tricuspid insufficiency as well.'" (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:44:10
Query 'PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization 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 'Copy previously sent by CRC on AM of 13 NOV. Please confirm it was not received and we will resend.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:02:24
User opened query 'PV Query: Please confirm that chronic kidney disease is included in medical history. If so, please list it in the medical history. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:07:13
User opened query 'PV Query: Please confirm if echocardiogram was performed. If so, please provide results.' (Site from Safety).		16 Nov 2020 18:06:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		16 Nov 2020 18:06:02
User opened query 'PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization 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).		16 Nov 2020 18:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
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)	16 Nov 2020 18:02:41
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. WE ARE STILL AWAITING FULL HOSPITAL D/C RECORDS AT THIS TIME. NO REPORT OF CHF IN PMHx PRIOR TO HEART ATTACK IN LATE OCTOBER.'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:03:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:55:09
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:53:28
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:15:49
User entered	(b) (4), (b) (6)	01 Dec 2020 13:15:49
'USA-US106-2020-mRNA-1273-P301000002'		
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:15:37
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 16:50:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Acute coronary syndrome - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	26 Feb 2021 22:57:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 22:57:55
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CORONARY ARTERY DISEASE WITH CALCIFIED LESION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:37:30
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:05:50
Comment added 'updated to "exacerbation" instead of "worsening"'. (b) (4)	Hollie Macenczak (b) (4)	19 Feb 2021 17:05:00
Data point term sent to Coder	System	19 Feb 2021 17:04:42
User entered 'ACUTE CORONARY SYNDROME, exacerbation' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	19 Feb 2021 17:04:27
Data point term sent to Coder	System	19 Feb 2021 16:56:33
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CORONARY ARTERY DISEASE WITH CALCIFIED LESION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'updated to include "worsening" (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 16:56:16
DataPoint Un-verified.	Hollie Macenczak (b) (4)	19 Feb 2021 16:56:02
Coding entries removed.	Hollie Macenczak (b) (4)	19 Feb 2021 16:56:02
User entered 'ACUTE CORONARY SYNDROME, worsening' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	19 Feb 2021 16:56:02

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CORONARY ARTERY DISEASE WITH CALCIFIED LESION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 07:13:47
	(b) (4), (b) (6)	06 Jan 2021 20:53:30
User closed query 'PV Query: Please update the event term to the final diagnosis upon review of medical records. ' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:33:47
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 07:21:17
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Chest pain is cardia-related - AE title updated to ACS' (Site from DM).	Hollie Macenczak (b) (4)	10 Dec 2020 17:35:00
Query 'PV Query: Please update the event term to the final diagnosis upon review of medical records. ' answered with 'updated' (Site from Safety).	Hollie Macenczak (b) (4)	10 Dec 2020 17:34:39
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Acute coronary syndrome - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 17:34:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 17:34:06
Data point term sent to Coder	System	10 Dec 2020 17:32:55

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
Coding entries removed.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User entered 'acute coronary syndrome' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 03:00:39
User opened query 'PV Query: Please update the event term to the final diagnosis upon review of medical records. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:48:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 21:45:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 21:45:03
	(b) (4)	
Data point term sent to Coder	System	20 Nov 2020 21:44:06
User entered 'chest pain'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:37:13
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:37:15
User entered 'No (N)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:37:19
User entered 'No (N)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:37:24
User entered '16 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:37:27
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
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.' canceled (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:23:48
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:42:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:53:44
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User entered 'No (N)' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:29
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:53:46
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User entered '20 Nov 2020' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:30
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:37:32
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Form: Adverse Events (4)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:52:41
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)	25 Nov 2020 16:49:27
User entered empty.	System	20 Nov 2020 21:43:16

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:53:48
DataPoint Un-verified.	Hollie Macenczak (b) (4)	05 Jan 2021 16:26:32
User entered 'Grade 4 (Grade 4)' reason for change:	Hollie Macenczak (b) (4)	05 Jan 2021 16:26:32
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:41
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:44:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 21:44:49
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	20 Nov 2020 21:44:49
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:43:16
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:37:58
User entered 'Yes (Y)'	Hollie Macenczak (b) (4) 	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:38:04
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:38:09
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:54:02
User closed query 'Per CDM re-query: Thank you for the response. Please provide discharge date once the data available. Leave the query open till the update is made else respond to clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 07:22:24
Query 'Per CDM re-query: Thank you for the response. Please provide discharge date once the data available. Leave the query open till the update is made else respond to clarify. Thank you.' answered with 'provided ' (Site from DM).	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:28
User closed query 'Requires inpatient or prolongation System 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).		10 Dec 2020 17:36:07
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		10 Dec 2020 17:36:07
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	10 Dec 2020 17:32:24
User opened query 'Per CDM re-query: Thank you for the response. Please provide discharge date once the data available. Leave the query open till the update is made else respond to clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:43:39
User closed query 'Per CDM RQ: Thank you for the response. Once, subject is discharged, please update Hospital Discharge Date appropriately, else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:43:26

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Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Per CDM RQ: Thank you for the response. Once, subject is discharged, please update Hospital Discharge Date appropriately, else clarify.' answered with 'Subject discharged on 20NOV2020 - medical records are pending at this time. No discharge summary to date.' (Site from DM).	Hollie Macenczak (b) (4)	23 Nov 2020 16:18:21
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)	23 Nov 2020 13:43:54
User opened query 'Per CDM RQ: Thank you for the response. Once, subject is discharged, please update Hospital Discharge Date appropriately, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:43:53
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 has no discharge date as he is still admitted.' (Site from System).	Hollie Macenczak (b) (4)	20 Nov 2020 21:44:37
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	20 Nov 2020 21:43:16
User entered 'I'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:54:05
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User entered '17 Nov 2020' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:40:59
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Form: Adverse Events (4)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:54:06
User entered '20 Nov 2020' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:07
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:54:08
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User entered 'Yes (Y)' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:05
User entered 'No (N)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:54:10
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User entered '4' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:11
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:41:14
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:41:16
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:41:28
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:41:31
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:41:33
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:41:34
User entered 'Not Applicable (NOT APPLICABLE)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:54:43
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:07
User entered '0' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:43
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:54:45
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:07
User entered '1' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:44
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM). Comment added 'For example, blood cultures was solicited to add to con proc list when in fact this is not a medical treatment but diagnostic in nature.' Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'In past queries, all procedures have been solicited whether diagnostic or medical treatment. Protocol/eCRF completion guidelines do not provide specific guidance on this. Therefore, since all procedures listed related to this SAE are pertinent to hospitalization and diagnosis, will continue to include in list.' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Hollie Macenczak (b) (4) Hollie Macenczak (b) (4)	24 Feb 2021 07:43:59 19 Feb 2021 17:25:13 19 Feb 2021 17:03:54
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 07:13:54
DataPoint Un-verified.	(b) (4), (b) (6) Hollie Macenczak (b) (4)	06 Jan 2021 20:54:46 10 Dec 2020 17:36:07
User entered '1' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:46
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:54:49
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)	11 Dec 2020 14:33:59
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 'outcome updated to reflect "resolved"' (Site from Safety).	Hollie Macenczak (b) (4)	10 Dec 2020 17:36:50
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:32:24
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)	25 Nov 2020 16:49:04
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:42:08
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR: Narrative = CLAUSTROPHOBIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:47:14
User closed query 'Per DM CLR: Narrative = ST ELEVATION WITH TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:47:12
User closed query 'Per DM CLR: Narrative = CARDIOMEGALY AND MULTIFOCAL PARENCHYMAL OPACITIES CONCERNING FOR PULMONARY EDEMA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:47:05
Query 'Per DM CLR: Narrative = CARDIOMEGALY AND MULTIFOCAL PARENCHYMAL OPACITIES CONCERNING FOR PULMONARY EDEMA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This description is related to chronic heart failure (already recorded and is currently ongoing)' (Site from DM).	Hollie Macenczak (b) (4)	02 Mar 2021 18:44:23
Query 'Per DM CLR: Narrative = ST ELEVATION WITH TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This does not need to be recorded separately as it is part of AE descriptions already recorded.' (Site from DM).	Hollie Macenczak (b) (4)	02 Mar 2021 18:43:31

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = CLAUSTROPHOBIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This does not need to be recorded as an AE' (Site from DM).	Hollie Macenczak (b) (4)	02 Mar 2021 18:39:55
User opened query 'Per DM CLR: Narrative = CLAUSTROPHOBIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:31:56
User opened query 'Per DM CLR: Narrative = ST ELEVATION WITH TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:31:51
User opened query 'Per DM CLR: Narrative = CARDIOMEGALY AND MULTIFOCAL PARENCHYMAL OPACITIES CONCERNING FOR PULMONARY EDEMA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:31:46
User closed query 'Per DM CLR: Narrative = NEGATIVE BLOOD CULTURES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:41:20
Query 'Per DM CLR: Narrative = NEGATIVE BLOOD CULTURES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'blood cultures added to conproc eCRF' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:05:43
User opened query 'Per DM CLR: Narrative = NEGATIVE BLOOD CULTURES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:13:27

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:55:37
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).		11 Dec 2020 14:34:23
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).		11 Dec 2020 14:34:14
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).		11 Dec 2020 14:34:09
DataPoint Un-verified.	Hollie Macenczak (b) (4)	10 Dec 2020 17:57:09

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT BEGAN HAVING CHEST PAIN AFTER SAFETY CALL WAS COMPLETED ON 16NOV2020 AND SOUGHT MEDICAL ATTENTION IN ED. TEAM WAS NOTIFIED ON 19NOV2020 OF ADMISSION TO HOSPITAL FOR EVALUATION OF "ARRHYTHMIA" AND "FLUTTER" PER SUBJECT DESCRIPTION. MEDICAL RECORDS PENDING. 10-DEC-2020 update after review of medical records: After 16-NOV-2020 presentation to ED with chest pain, subject was found to have acute coronary syndrome causing acute systolic heart failure. He was found to have new cardiomegaly and multifocal parenchymal opacities concerning for pulmonary edema. Due to leukocytosis (although he was afebrile with negative blood cultures), he was treated empirically for pneumonia in ED. He was also found to have ST elevation with tachycardia (HR in 150s) with underlying atrial fibrillation. Started on nitroglycerin and heparin drip. He was also loaded with amiodarone. Unable to complete CV MRI due to claustrophobia during admission. Symptoms had resolved by 20-NOV-2020 and was discharged stable. He will continue with ASA, Plavix and Xarelto, beta blocker, statin. Will follow up with outpatient cardiologist.' reason for change: New Information	Hollie Macenczak (b) (4)	10 Dec 2020 17:57:09
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Discharge date provided above, narrative updated accordingly.' (Site from Safety).	Hollie Macenczak (b) (4)	10 Dec 2020 17:42:52
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' answered with 'Included in medical records sent to Safety_Moderna@iqvia.com' (Site from Safety).	Hollie Macenczak (b) (4)	10 Dec 2020 17:42:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[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 'Medical records sent to Safety_Moderna@iqvia.com for review. Study team will provide updated medications on concomitant medication list. There were no surgical treatments. CV MRI attempted but unable to be completed due to subject claustrophobia. Echocardiogram completed as well as telemetry, various ECGs, and various chest X-rays.' (Site from Safety).	Hollie Macenczak (b) (4)	10 Dec 2020 17:42:10
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:50:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:49:56
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)	25 Nov 2020 16:49:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:42:23
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 21:47:08
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 21:47:08

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject began having chest pain after safety call was completed on 16NOV2020 and sought medical attention in ED. Team was notified on 19NOV2020 of admission to hospital for evaluation of "arrhythmia" and "flutter" per subject description. Medical records pending.' reason for change: New Information	Hollie Macenczak (b) (4)	20 Nov 2020 21:47:08
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 21:43:16
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 17:32:24
User entered '0'	System	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:06:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 15:45:25
User entered	(b) (4), (b) (6)	11 Dec 2020 15:45:21
'USA-US106-2020-mRNA-1273-P301000002'		

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'For coding purpose, please split ATRIAL FLUTTER/ ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE into separate entries. 1. ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE and 2. ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE or provide ONE diagnosis.' (Site from Coder).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:55:35
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of IRREGULAR HEART RHYTHM. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:55:07
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:06:34
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of IRREGULAR HEART RHYTHM. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'There is no history or documentation of prior atrial fibrillation. "irregular heart rhythm" was reported by subject. The nature/type of this was unknown.' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:26:14
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of IRREGULAR HEART RHYTHM. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:15:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
Query 'For coding purpose, please split ATRIAL FLUTTER/ ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE into separate entries. 1. ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE and 2. ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE or provide ONE diagnosis.' answered with 'separated entries to "ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE" and "paroxysmal atrial flutter"' (Site from Coder).	Hollie Macenczak (b) (4)	22 Jan 2021 21:34:52
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation with rapid ventricular response - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 21:33:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	22 Jan 2021 21:33:16
Data point term sent to Coder	System	22 Jan 2021 21:32:34
DataPoint Un-verified.	Hollie Macenczak (b) (4)	22 Jan 2021 21:32:21
Coding entries removed.	Hollie Macenczak (b) (4)	22 Jan 2021 21:32:21
User entered 'ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	22 Jan 2021 21:32:21
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:07:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 21:07:04
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:07:02
User opened query 'For coding purpose, please split ATRIAL FLUTTER/ ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE into separate entries. 1. ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE and 2. ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE or provide ONE diagnosis.' (Site from Coder).	(b) (4), (b) (6)	15 Dec 2020 19:53:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation with rapid ventricular response - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:47:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:47:42
Data point term sent to Coder	System	11 Dec 2020 21:27:44
Coding entries removed.	Hollie Macenczak (b) (4)	11 Dec 2020 21:27:23
User entered 'ATRIAL FLUTTER/ atrial fibrillation with rapid ventricular response' reason for change:	Hollie Macenczak (b) (4)	11 Dec 2020 21:27:23
Data Entry Error		
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Paroxysmal atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:09:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:09:51
Data point term sent to Coder	System	10 Dec 2020 20:08:40
User entered 'paroxysmal atrial flutter'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:11
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:14
User entered 'No (N)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:07:15
User entered 'No (N)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:07:19
User entered '16 Nov 2020'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:07:20
User entered empty.	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:34:48
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Feb 2021 19:34:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:22:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 21:27:23
User entered 'No (N)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:31:29
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'NEW BASELIE ESTABLISHED. CLEARED BY CARDIOLOGY ON 14JAN 2021 FOR REVAX.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 19:38:37
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 19:34:48
User entered '14 Jan 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Feb 2021 19:34:48
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 23:46:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:22:33
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Dec 2020 21:28:37
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	11 Dec 2020 21:28:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		11 Dec 2020 21:27:23
User entered empty; reason for change Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 21:27:23
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:22:35
User entered empty.	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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. ' canceled (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 23:45:47
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)	17 Dec 2020 15:26:18
User entered empty.	System	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:22:46
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	05 Jan 2021 16:27:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:22:48
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:22:51
User entered '0'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

US3482284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:22:53
User entered '0'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:23:18
User entered 'I'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:23:19
User entered '17 Nov 2020'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:23:21
User entered '20 Nov 2020'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

US3482284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:23:23
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

US3482284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:23:24
User entered '4'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

US3482284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:23:27
User entered '0'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

US3482284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:23:29
User entered '0'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:31:48
User entered '0'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:32:00
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:32:03
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:34:48
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	19 Feb 2021 19:34:48
reason for change: New Information		
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:32:05
User entered 'Not Applicable (NOT APPLICABLE)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:32:20
User entered '0'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

US3482284

Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:32:22
User entered 'I'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:53:42
Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'Past queries have included all procedures (both diagnostic and medical treatments). All procedures listed corresponding to this SAE are pertinent to hospitalization and diagnosis.' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:27:39
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:16:00
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:15:10
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Con procedure was indeed recorded on 11-DEC-2020: "echocardiogram" performed on 17-NOV-2020 which is consistent with the time frame of recorded AE.' (Site from DM).	Hollie Macenczak (b) (4)	02 Feb 2021 20:27:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 04:16:53
	(b) (4), (b) (6)	06 Jan 2021 21:32:24
User entered 'I'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:31:45
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'SEE NOTES-- NEW BASELINE DX.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 19:39:35
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 19:34:48
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Feb 2021 19:34:48
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 23:46:28
User closed query 'PV Query: Thank you for confirming new baseline would be considered 20 Nov 2020. Please update end date and outcome accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:08:22
Query 'PV Query: Thank you for confirming new baseline would be considered 20 Nov 2020. Please update end date and outcome accordingly.' answered with 'PARTICIPANT CONTINUES ON CARDIAC MEDS TO CONTROL THE ARRHYTHMIAS. ARE YOU REQUESTING WE RESOLVE OUT THE QUERY DESPITE THIS?' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:47:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for confirming new baseline would be considered 20 Nov 2020. Please update end date and outcome accordingly.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:33:28
User closed query 'Thank you for reporting outcome for the event was not expected to recover. Has a new baseline has been achieved? If so please provide the event end date (when the new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:53:35
Query 'Thank you for reporting outcome for the event was not expected to recover. Has a new baseline has been achieved? If so please provide the event end date (when the new baseline has been achieved), when available.' answered with 'The date for new baseline would be considered would be 20-NOV-2020 (discharge date). Should I changed the outcome based on this new baseline?' (Site from Safety).	Hollie Macenczak (b) (4)	29 Jan 2021 19:50:57
User opened query 'Thank you for reporting outcome for the event was not expected to recover. Has a new baseline has been achieved? If so please provide the event end date (when the new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:29:27
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)	25 Jan 2021 16:52:09
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 continues to take PO amiodarone to control and is being follow by cardiology. Resolution is not expected (no ablation is scheduled as of now).' (Site from Safety).	Hollie Macenczak (b) (4)	22 Jan 2021 21:31:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:32:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Outcome](#)

Audit	User	Time (GMT)
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)	17 Dec 2020 15:25:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 21:28:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	19 Feb 2021 19:37:49
	(b) (4), (b) (6)	19 Feb 2021 19:37:49
User entered '19FEB 2021 UPDATE: WAS CLEARED BY CARDIOLOGIST ON 14JAN 2021 FOR REVAX. ARRHYTHMIA CONTROLLED ON CONTINUED CARDIAC MEDS. DEEMED STABLE, NEW BASELINE ESTABLISHED.'	(b) (4), (b) (6)	19 Feb 2021 19:37:49
reason for change: Per Query Resolution		
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	19 Feb 2021 19:34:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:32:42
User entered empty.	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR: Narrative = OUTPATIENT ABLATION WITHIN 2 MONTHS. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:47:59
Query 'Per DM CLR: Narrative = OUTPATIENT ABLATION WITHIN 2 MONTHS. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' answered with 'This was not performed as it was deemed not necessary due to treatment with amiodarone. ' (Site from DM).	Hollie Macenczak (b) (4)	02 Mar 2021 18:36:16
User opened query 'Per DM CLR: Narrative = OUTPATIENT ABLATION WITHIN 2 MONTHS. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:44:09
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:06:28
User closed query 'Per DM CLR: Narrative = PLANS TO FOLLOW UP WITH OUTPATIENT ABLATION WITHIN 2 MONTHS. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:37:30
Query 'Per DM CLR: Narrative = PLANS TO FOLLOW UP WITH OUTPATIENT ABLATION WITHIN 2 MONTHS. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' answered with 'This has not been completed - subject reports that cardiologist does not recommend at this time.' (Site from DM).	Hollie Macenczak (b) (4)	17 Feb 2021 19:19:44
User opened query 'Per DM CLR: Narrative = PLANS TO FOLLOW UP WITH OUTPATIENT ABLATION WITHIN 2 MONTHS. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:15:01

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per query response, it was noted paroxysmal atrial flutter to reflect a start day of 11/5 (ongoing). Please confirm if Paroxysmal atrial flutter should be entered as a separate event with this onset date and update the eCRF accordingly. Thank you' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:53:27
User closed query 'PV Query: Thank you for reporting trial flutter/ atrial fibrillation with rapid ventricular response were separated. Please confirm if the event atrial flutter should be reported as a separate SAE as it is not currently listed. Please update the eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:53:06
Query 'PV Query: Per query response, it was noted paroxysmal atrial flutter to reflect a start day of 11/5 (ongoing). Please confirm if Paroxysmal atrial flutter should be entered as a separate event with this onset date and update the eCRF accordingly. Thank you' answered with '"Atrial flutter" and "paroxysmal atrial flutter" are the same diagnosis with a start date of 11/5. "Paroxysmal" was added after last query to more accurately reflect cardiology note after re-review of medical records.' (Site from Safety).	Hollie Macenczak (b) (4)	29 Jan 2021 19:58:22
Query 'PV Query: Thank you for reporting trial flutter/ atrial fibrillation with rapid ventricular response were separated. Please confirm if the event atrial flutter should be reported as a separate SAE as it is not currently listed. Please update the eCRF accordingly.' answered with 'Atrial fibrillation was recorded as SAE #6 but updated to reflect "paroxysmal" to better coincide with cardiology notes included in medical records.' (Site from Safety).	Hollie Macenczak (b) (4)	29 Jan 2021 19:52:47
User opened query 'PV Query: Per query response, it was noted paroxysmal atrial flutter to reflect a start day of 11/5 (ongoing). Please confirm if Paroxysmal atrial flutter should be entered as a separate event with this onset date and update the eCRF accordingly. Thank you' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:29:18

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for reporting trial flutter/ atrial fibrillation with rapid ventricular response were separated. Please confirm if the event atrial flutter should be reported as a separate SAE as it is not currently listed. Please update the eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:29:02
User closed query 'PV Query: Did the event atrial flutter/atrial fibrillation with rapid ventricular response occur on 05-NOV-2020 and continue until 19-NOV-2020? If so, please confirm the onset date.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 16:52:17
User closed query 'PV Query: Please consider updating the event of atrial flutter/ atrial fibrillation with rapid ventricular response to the final diagnosis. If both diagnosis are to be captured as SAE's please consider updating the term to "atrial flutter" and reporting a separate SAE of "atrial fibrillation with rapid ventricular response". If to remain as SAE of atrial flutter/ atrial fibrillation with rapid ventricular response please explain. ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 16:52:13
Query 'PV Query: Did the event atrial flutter/atrial fibrillation with rapid ventricular response occur on 05-NOV-2020 and continue until 19-NOV-2020? If so, please confirm the onset date.' answered with 'SAEs updated to reflect start date of atrial fib with RVR start date of 11/16 (ongoing) AND paroxysmal atrial flutter to reflect a start day of 11/5 (ongoing)' (Site from Safety).	Hollie Macenczak (b) (4)	22 Jan 2021 21:37:04
Query 'PV Query: Please consider updating the event of atrial flutter/ atrial fibrillation with rapid ventricular response to the final diagnosis. If both diagnosis are to be captured as SAE's please consider updating the term to "atrial flutter" and reporting a separate SAE of "atrial fibrillation with rapid ventricular response". If to remain as SAE of atrial flutter/ atrial fibrillation with rapid ventricular response please explain. ' answered with 'separated SAEs per query request' (Site from Safety).	Hollie Macenczak (b) (4)	22 Jan 2021 21:35:22
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 21:42:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:42:22

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the event atrial flutter/atrial fibrillation with rapid ventricular response occur on 05-NOV-2020 and continue until 19-NOV-2020? If so, please confirm the onset date.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:25:02
User opened query 'PV Query: Please consider updating the event of atrial flutter/ atrial fibrillation with rapid ventricular response to the final diagnosis. If both diagnosis are to be captured as SAE's please consider updating the term to "atrial flutter" and reporting a separate SAE of "atrial fibrillation with rapid ventricular response". If to remain as SAE of atrial flutter/ atrial fibrillation with rapid ventricular response please explain. ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:24:19
User entered 'SUBJECT HAD INCREASED DYSPNEA AND NEW CHEST PAIN ON 16-NOV-2020 IN WHICH HE PRESENTED TO ED. HE WAS TACHYCARDIC WITH HR IN 150S WITH UNDERLYING ATRIAL FLUTTER. HE WAS STARTED ON HEPARIN DRIP AND UNDERWENT AMIODARONE LOADING DURING ADMISSION. PLANS TO FOLLOW UP WITH OUTPATIENT ABLATION WITHIN 2 MONTHS. Continues treatment for condition.' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 21:27:23
User entered 'Subject had increased dyspnea and new chest pain on 16-NOV-2020 in which he presented to ED. He was tachycardic with HR in 150s with underlying atrial flutter. He was started on heparin drip and underwent amiodarone loading during admission. Flutter resolved by 18-NOV-2020. Plans to follow up with outpatient ablation within 2 months.'	Hollie Macenczak (b) (4)	10 Dec 2020 20:08:07

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Dec 2020 20:08:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:02:41
User entered 'USA-US106-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	19 Feb 2021 20:02:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Paroxysmal atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 21:54:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 21:54:11
	(b) (4)	
Data point term sent to Coder	System	22 Jan 2021 21:52:47
User entered 'Paroxysmal atrial flutter'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'No (N)'	Hollie Macenczak (b) (4) 	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'No (N)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '05 Nov 2020'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered empty.	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Un-verified.	(b) (4) Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
User entered 'No (N)' reason for change: New Information	Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Un-verified.	(b) (4) Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
User entered '14 Jan 2021' reason for change: New Information	Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered empty.	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered empty.	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '0'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '0'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'I'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '05 Nov 2020'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

US3482284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '07 Nov 2020'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '3'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

US3482284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '0'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

US3482284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '0'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '0'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 20:00:02
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	19 Feb 2021 20:00:02
reason for change: New Information		
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Not Applicable (NOT APPLICABLE)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered '0'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

US3482284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'I'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'Entered per IQVIA request I directive on SAE documentation in the eCRF. Discussed with RSM today and confirmed that diagnostic procedure info needs to be entered in RAVE for any SAE.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:15:59
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:59:02
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:45:31
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'I'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Un-verified.	(b) (4)	
	Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
reason for change: New Information		
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
	(b) (4)	
User entered 'New baseline A fib with paroxysmal A flutter - controlled on amiodarone.' reason for change: New Information	Hollie Macenczak (b) (4)	19 Feb 2021 19:46:44
DataPoint Un-verified.	Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
User entered '19FEB 2021 UPDATE: WAS CLEARED BY CARDIOLOGIST ON 14JAN 2021 FOR REVAX. ARRHYTHMIA CONTROLLED ON CONTINUED CARDIAC MEDS. DEEMED STABLE, NEW BASELINE ESTABLISHED.'	Hollie Macenczak (b) (4)	19 Feb 2021 19:44:33
reason for change: New Information		
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered empty.	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:15:58
User entered 'Subject presented to ED with gradual onset of intermittent chest pain and dyspnea on exertion. Found to be in atrial flutter in ED. Cardioversion was planned during admission but due to delay in initiating procedure, subject did not want to wait and left hospital AMA. Being followed by cardiology.'	Hollie Macenczak (b) (4)	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Jan 2021 21:51:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:50:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Jan 2021 21:51:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:50:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:56:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:37:40
User closed query 'Per ETRTR: Medications and procedures were done for SAE "Myocardial Infarction" according to SAE CRF. Please update ConMeds and ConProceudres as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:04:17
Query 'Per ETRTR: Medications and procedures were done for SAE "Myocardial Infarction" according to SAE CRF. Please update ConMeds and ConProceudres as applicable, thanks.' answered with 'New meds and d/c'd meds updated and ongoing' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:29:59
User opened query 'Per ETRTR: Medications and procedures were done for SAE "Myocardial Infarction" according to SAE CRF. Please update ConMeds and ConProceudres as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:32:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:21:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 16:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:04:40
Data point term sent to Coder	System	19 Oct 2020 16:03:42
User entered 'Atorvastatin'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	06 Nov 2020 17:42:31
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	06 Nov 2020 17:42:31
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Nov 2020 17:42:25
User entered '30 Oct 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	06 Nov 2020 17:42:25
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User entered '1'	System	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User entered '1'	System	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:53
User entered '804 (804)'	System	19 Oct 2020 16:03:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Dec 2020 20:51:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 20:51:00
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	01 Dec 2020 20:50:44 01 Dec 2020 20:49:58
User entered 'METOPROLOL XL' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 20:49:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:05:41
Data point term sent to Coder User entered 'Metoprolol'	System (b) (4), (b) (6)	19 Oct 2020 16:04:44 19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '25'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 16:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:06:45
Data point term sent to Coder	System	19 Oct 2020 16:05:46
User entered 'Losartan'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '50'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:07:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:07:34
Data point term sent to Coder	System	19 Oct 2020 16:06:50
User entered 'Aspirin'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Heart Health'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '81'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Oct 2020 10:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:19:32
Data point term sent to Coder	System	19 Oct 2020 16:07:52
User entered 'Triameterene HCTZ'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '37.5/25'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5 Nov 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:38
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User entered '1'	System	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User entered '1'	System	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:36
User entered '804 (804)'	System	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
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)	19 Oct 2020 16:09:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:09:24
Data point term sent to Coder User entered 'Amlodipine'	System (b) (4), (b) (6)	19 Oct 2020 16:08:52 19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	10 Nov 2020 16:30:58
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Nov 2020 16:28:41
User entered '5 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 16:28:41
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User entered '1'	System	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User entered '1'	System	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:30
User entered '804 (804)'	System	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: DESCOVY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:11:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:11:21
Data point term sent to Coder	System	19 Oct 2020 16:09:55
User entered 'Descovy'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Missed - Per DM CLR: Please review indication if this was given as prophylaxis. If so, please remove recorded MH#11 'HIV PROPHYLAXIS' Else, please update recorded condition on both CM and MH to remove 'prophylaxis' and update Prophylaxis field to NO. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:16:59
Query 'Missed - Per DM CLR: Please review indication if this was given as prophylaxis. If so, please remove recorded MH#11 'HIV PROPHYLAXIS' Else, please update recorded condition on both CM and MH to remove 'prophylaxis' and update Prophylaxis field to NO. ' answered with 'HIV prophylaxis is a ICD-10 codeable medical condition: Z20.6 (Contact with and (suspected) exposure to HIV). Certain labs and follow-up are part & parcel to HIV prophylaxis and being on the meds used for the purpose, as they can cause kidney issues, bone loss, etc. It does not seem medically appropriate to remove this from ppt's history, as it is pertinent to his health. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:06:40
User opened query 'Missed - Per DM CLR: Please review indication if this was given as prophylaxis. If so, please remove recorded MH#11 'HIV PROPHYLAXIS' Else, please update recorded condition on both CM and MH to remove 'prophylaxis' and update Prophylaxis field to NO. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:57:50
User entered 'HIV Prophylaxis'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:44:08
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'CORRECTED.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:33:06
User entered '25/200' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 21:32:58
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:25:47
User entered '25'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:12:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:12:24
Data point term sent to Coder	System	19 Oct 2020 16:10:56
User entered 'Zolpidem'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Insomnia'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: HERBAL ANTI OBESITY PREPARATIONS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Jan 2021 23:42:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:42:31
Data point term sent to Coder	System	01 Dec 2020 14:24:03
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	01 Dec 2020 14:24:02
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with ' Name of supplement updated to reflect full name from bottle.' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 14:24:02
Data point term sent to Coder	System	01 Dec 2020 14:12:50
User entered 'RED VOLT EXTREME FAT BURNER' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 14:12:37
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:21:10
Data point term sent to Coder	System	19 Oct 2020 16:11:59
User entered 'Red Volt Pre-Workout Supplement'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:45:11
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'USED FOR WEIGHT LOSS.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:33:39
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:25:15
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Weight Loss'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '2'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
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	01 Dec 2020 14:13:02
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 14:13:02
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 14:12:37
User entered empty; reason for change New Information	(b) (4), (b) (6)	01 Dec 2020 14:12:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	04 Dec 2020 22:42:33
User entered '10 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 22:42:33
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	01 Dec 2020 14:13:02
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User entered empty.	System	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User entered empty.	System	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:10
User entered empty.	System	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ANDROGRAPHIS PANICULATA;ECHINACEA PURPUREA ROOT;OLEA EUROPAEA LEAF, PRODUCTSYNONYM: IMMUNE SUPPORT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:23:20
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 Oct 2020 16:23:20
Data point term sent to Coder	System	19 Oct 2020 16:14:02
User entered 'Immune Support Vitamin'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Health Maintenance'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 17:50:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 17:50:52
Data point term sent to Coder	System	19 Feb 2021 17:36:39
Coding entries removed.	Hollie Macenczak (b) (4)	19 Feb 2021 17:35:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 00:31:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 00:31:52
Data point term sent to Coder	System	11 Dec 2020 17:11:53
Coding entries removed.	Hollie Macenczak (b) (4)	11 Dec 2020 17:11:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:19:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:19:28
Data point term sent to Coder	System	06 Nov 2020 17:52:55
User entered 'Heparin'	Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:59:51
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'Indication updated' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:35:19
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:39:49
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'treatment of clot - ASSOCIATED WITH AE #1' reason for change: Per Query Resolution	(b) (4) Hollie Macenczak (b) (4)	19 Feb 2021 17:35:50
User entered 'clot prevention - associated with AE #1' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 17:11:41
User entered 'AE # 1 (mYOCARDIAL INFARCTION)'	Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5000'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'UNITS'	Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User entered empty.	System	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User entered empty.	System	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:32
User entered empty.	System	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:40:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:40:43
Data point term sent to Coder	System	11 Dec 2020 17:12:54
Data point term sent to Coder	System	01 Dec 2020 20:04:23
Coding entries removed.	(b) (4), (b) (6)	01 Dec 2020 20:04:12
User entered 'NITROGLYCERIN' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 20:04:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:31:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:31:28
Data point term sent to Coder	System	06 Nov 2020 18:03:14
User entered 'Nitroglycerine'	Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'chest pain - associated with AE #1' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:12:32
User entered 'Myocardial infarction (AE#1)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please review recorded Dose and Unit as they appear to be the dosage formulation rather than the actual dose. Please review and update to provide the actual dose as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 02:01:27
Query 'Per DM CLR: Please review recorded Dose and Unit as they appear to be the dosage formulation rather than the actual dose. Please review and update to provide the actual dose as appropriate. Otherwise, clarify.' answered with 'Updated with actual dose ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 15:55:27
User entered '0.4' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 15:55:18
User opened query 'Per DM CLR: Please review recorded Dose and Unit as they appear to be the dosage formulation rather than the actual dose. Please review and update to provide the actual dose as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 18:01:46
User entered '50'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 15:55:18
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:55:18
User entered 'Mg/250 ml'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:27:03
User entered '20 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:27:03
User entered '20 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User entered empty.	System	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User entered empty.	System	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:10
User entered empty.	System	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 21:09:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:09:24
Data point term sent to Coder	System	06 Nov 2020 18:04:17
User entered 'Aspirin'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'AE#1 (myocardial infarction)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '324' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:53:22
User entered '325'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	06 Nov 2020 18:03:34
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	06 Nov 2020 18:03:34
User entered 'once (ONCE)'	System	06 Nov 2020 18:03:18
	Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	06 Nov 2020 18:03:34
User entered '20 Oct 2020'	(b) (4)	
	Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User entered empty.	System	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User entered empty.	System	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:46
User entered empty.	System	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 23:46:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:46:23
Data point term sent to Coder	System	06 Nov 2020 18:05:18
User entered 'Clopidogrel'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'AE#1 (myocardial infarction)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '75'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'mg (mg)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'once daily (QD)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '30 Oct 2020'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '0'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:04:30
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Jan 2021 16:30:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 16:30:07
Data point term sent to Coder	System	19 Jan 2021 16:29:18
Coding entries removed.	(b) (4), (b) (6)	19 Jan 2021 16:28:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:08:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:08:20
Data point term sent to Coder	System	06 Nov 2020 18:07:23
User entered 'Seroquel'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'INSOMNIA and Bipolar disorder'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 16:28:57
User entered 'insomnia'	Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '200'	Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'twice daily (BID)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '30 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User entered '2'	System	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User entered '1'	System	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:27:20
User entered '804 (804)'	System	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 18:09:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:09:21
Data point term sent to Coder	System	06 Nov 2020 18:08:24
User entered 'seroquel'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'insomnia'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '100'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'mg (mg)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'once daily (QD)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '31 Oct 2020'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '0'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per CDM re-query: Response noted; However please confirm if the already existing condition worsened; If so, update the indication and AE term to reflect "worsening". Else confirm the condition is not worsening in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:06:45
Query 'Per CDM re-query: Response noted; However please confirm if the already existing condition worsened; If so, update the indication and AE term to reflect "worsening". Else confirm the condition is not worsening in query response. ' answered with 'There is nothing per subject or per records that there is a "worsening" of hyperlipidemia. The increase in dose from 20mg to 40mg was in response to the myocardial infarction listed as SAE #1. It would not be an appropriate assessment to include "worsening of hyperlipidemia" as an additional AE.' (Site from DM).	Hollie Macenczak (b) (4)	02 Feb 2021 20:42:06
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:02:37
User opened query 'Per CDM re-query: Response noted; However please confirm if the already existing condition worsened; If so, update the indication and AE term to reflect "worsening". Else confirm the condition is not worsening in query response. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:02:34
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'Increase in dose related to AE #1 (myocardial infarction)' (Site from DM).	Hollie Macenczak (b) (4)	29 Jan 2021 20:00:50

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 18:04:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Dec 2020 19:37:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	11 Dec 2020 17:17:58
	Hollie Macenczak (b) (4)	11 Dec 2020 17:17:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 18:10:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder User entered 'Atorvastatin'	System	06 Nov 2020 18:09:25
	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please note that "HYPERLIPIDEMIA" is not recorded on AE as one of the condition that existed during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:02:12
Query 'Per DM CLR: Please note that "HYPERLIPIDEMIA" is not recorded on AE as one of the condition that existed during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Subject took this medication at baseline but dose was increased due to complications surrounding AE #1. Hyperlipidemia does not need to be recorded as an additional AE.' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:38:02
User opened query 'Per DM CLR: Please note that "HYPERLIPIDEMIA" is not recorded on AE as one of the condition that existed during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:40:55
User entered 'HYPERLIPIDEMIA - associated with AE #1' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 17:17:01
User entered 'hyperlipidemia'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '40'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'mg (mg)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'once daily (QD)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '30 Oct 2020'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '0'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Sarah Bechnak (b) (4)	06 Nov 2020 18:08:40
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:08:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 01:19:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 01:19:39
Data point term sent to Coder Coding entries removed.	System Hollie Macenczak (b) (4)	02 Feb 2021 20:30:58 02 Feb 2021 20:30:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:23
Data point term sent to Coder	System	11 Dec 2020 17:17:58
Data point term sent to Coder	System	01 Dec 2020 20:55:51
User entered 'LASIX'	(b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'SHORTNESS OF BREATH, WORSENING' reason for change: Per Query Resolution	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 20:30:29
User entered 'HEART FAILURE - associated with AE #2' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 17:17:18
User entered 'HEART FAILURE'	(b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '40'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 16:50:30
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	01 Dec 2020 21:23:34
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	01 Dec 2020 21:23:34
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	01 Dec 2020 20:55:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 16:50:30
User entered '5 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 21:23:34
User entered '6 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User entered '1'	System	11 Dec 2020 16:50:30
User entered empty.	System	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User entered '1'	System	11 Dec 2020 16:50:30
User entered empty.	System	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:10
User entered '804 (804)'	System	11 Dec 2020 16:50:30
User entered empty.	System	01 Dec 2020 20:55:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jan 2021 20:09:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 20:09:28
Data point term sent to Coder Coding entries removed.	System Hollie Macenczak (b) (4)	29 Jan 2021 20:08:06 29 Jan 2021 20:07:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 17:21:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 17:21:52
Data point term sent to Coder Coding entries removed.	System Hollie Macenczak (b) (4)	11 Dec 2020 17:21:02 11 Dec 2020 17:20:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 21:28:51

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Dec 2020 21:28:51
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	01 Dec 2020 21:28:31
User entered 'XARELTO'	(b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'CLOT PREVENTION - ASSOCIATED WITH AE #3' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	29 Jan 2021 20:07:36
User entered 'CLOT PREVENTION - associated with AE #2' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 17:20:07
User entered 'CLOT PREVENTION'	(b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:18:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'This medication was started during associated hospitalized and AE but is ongoing due to underlying cardiovascular history' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:48:19
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:44:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 21:27:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 18:40:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:40:43
Data point term sent to Coder Coding entries removed.	System Hollie Macenczak (b) (4)	11 Dec 2020 17:21:02 11 Dec 2020 17:20:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 21:47:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 21:47:52
Data point term sent to Coder User entered 'NITROGLYCERIN'	System (b) (4), (b) (6)	01 Dec 2020 21:46:56 01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
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	01 Dec 2020 21:49:18
User entered 'No (N)' reason for change: Data Entry Error	System	01 Dec 2020 21:49:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 21:49:18
User entered empty.	System	01 Dec 2020 21:46:18
	(b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'CHEST PAIN - associated with AE #1' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 17:20:48
User entered 'CHEST PAIN'	(b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0.4'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'SUBLINGUAL'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '31 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 21:46:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 00:46:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 00:46:34
Data point term sent to Coder	System	02 Feb 2021 20:34:01
Coding entries removed.	Hollie Macenczak (b) (4)	02 Feb 2021 20:33:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 00:30:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 00:30:51
Data point term sent to Coder	System	11 Dec 2020 17:34:10
Coding entries removed.	Hollie Macenczak (b) (4)	11 Dec 2020 17:33:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 21:54:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 21:54:54
Data point term sent to Coder	System	01 Dec 2020 21:54:04
User entered 'HEPARIN'	(b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'SHORTNESS OF BREATH, WORSENING' reason for change: Per Query Resolution	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 20:33:25
User entered 'CLOT PREVENTION - associated with AE #2' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 17:33:54
User entered 'CLOT PREVENTION'	(b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '3700'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'UNITS'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User entered empty.	System	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User entered empty.	System	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:44
User entered empty.	System	01 Dec 2020 21:53:39

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Dec 2020 20:38:05
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 Dec 2020 20:38:05
Data point term sent to Coder	System	11 Dec 2020 17:24:04
Coding entries removed.	Hollie Macenczak (b) (4)	11 Dec 2020 17:23:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:06:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:06:59
Data point term sent to Coder	System	01 Dec 2020 21:57:06
User entered 'DOXYCYCLINE'	(b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'SUSPECTED PNEUMONIA - associated with AE #3' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 17:23:45
User entered 'SUSPECTED PNEUMONIA'	(b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '100'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '7 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User entered '2'	System	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User entered '1'	System	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:57
User entered '804 (804)'	System	01 Dec 2020 21:56:37

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 09:35:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 09:35:14
Data point term sent to Coder Coding entries removed.	System Hollie Macenczak (b) (4)	11 Dec 2020 17:32:08 11 Dec 2020 17:31:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 18:24:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 18:24:46
Data point term sent to Coder User entered 'CEFTRIAXONE'	System (b) (4), (b) (6)	01 Dec 2020 21:58:10 01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'SUSPECTED PNEUMONIA - associated with AE #3' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:31:23
User entered 'SUSPECTED PNEUMONIA'	(b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '7 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User entered '1'	System	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User entered '1'	System	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:47
User entered '804 (804)'	System	01 Dec 2020 21:57:42

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 21:01:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:01:46
Data point term sent to Coder	System	11 Dec 2020 17:32:08
Data point term sent to Coder	System	01 Dec 2020 22:01:14
User entered 'HEPARIN'	(b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'CLOT PREVENTION - associated with AE #3' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:32:01
User entered 'CLOT PREVENTION'	(b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17.4'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'UNITS PER KG PER HOUR'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User entered empty.	System	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User entered empty.	System	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:03
User entered empty.	System	01 Dec 2020 22:00:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 21:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 21:46:32
Data point term sent to Coder	System	02 Feb 2021 20:33:00
Coding entries removed.	Hollie Macenczak (b) (4)	02 Feb 2021 20:32:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Dec 2020 15:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Dec 2020 15:48:54
Data point term sent to Coder	System	11 Dec 2020 17:36:11
User entered 'aspirin'	Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'SHORTNESS OF BREATH, WORSENING' reason for change: Per Query Resolution	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 20:32:54
User entered 'chest pain protocol - associated with AE #2'	Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '324'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '05 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '05 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User entered empty.	System	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User entered empty.	System	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:17
User entered empty.	System	11 Dec 2020 17:35:50

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:55
Data point term sent to Coder	System	11 Dec 2020 17:40:14
User entered 'lasix'	Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat and not the drug class. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:10:14
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat and not the drug class. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'The condition is heart failure - Lasix is an appropriate medication to be used for edema r/t to HF.' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:42:27
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat and not the drug class. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:45:19
User entered 'diuretic - associated with AE #3'	Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '60'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)' reason for change: New Information	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:24:48
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '14 Dec 2020' reason for change: New Information	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 22:24:48
User entered empty.	Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User entered '1'	System	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User entered '1'	System	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:04
User entered '804 (804)'	System	11 Dec 2020 17:39:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
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)	12 Dec 2020 15:40:49
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 Dec 2020 15:40:49
Data point term sent to Coder	System	11 Dec 2020 19:58:35
Data point term sent to Coder	System	11 Dec 2020 19:54:29
User entered 'amiodarone'	Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'ATRIAL FLUTTER/FIBRILLATION	(b) (4)	
- associated with AE #5' reason for change: Data	Hollie Macenczak (b) (4)	11 Dec 2020 19:58:00
Entry Error		
User entered 'atrial flutter/fibrillation'	Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '400'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'twice daily (BID)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '19 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:18:27
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '08 Dec 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:18:27
User entered empty.	Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User entered '2'	System	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User entered '1'	System	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:19:58
User entered '804 (804)'	System	11 Dec 2020 19:53:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: ADENOSINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Dec 2020 15:23:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Dec 2020 15:23:47
Data point term sent to Coder	System	11 Dec 2020 19:58:34
Data point term sent to Coder	System	11 Dec 2020 19:56:32
User entered 'adenosine'	Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'ATRIAL FLUTTER/FIBRILLATION	(b) (4)	
- associated with AE #5' reason for change: Data	Hollie Macenczak (b) (4)	11 Dec 2020 19:58:33
Entry Error		
User entered 'atrial flutter/fibrillation'	Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '6-12'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'as needed (PRN)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '19 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '19 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User entered empty.	System	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User entered empty.	System	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:20:02
User entered empty.	System	11 Dec 2020 19:55:34

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Dec 2020 15:44:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Dec 2020 15:44:48
Data point term sent to Coder	System	11 Dec 2020 19:59:36
Data point term sent to Coder	System	11 Dec 2020 19:57:32
User entered 'aspirin'	Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'CHEST PAIN PROTOCOL - associated with AE #4' reason for change: Data Entry Error	(b) (4)	
	Hollie Macenczak (b) (4)	11 Dec 2020 19:58:49
User entered 'chest pain protocol'	Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (ex. 325mg). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:11:51
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (ex. 325mg). Please correct the dosage or provide explanation for alternate dosage. ' answered with 'This is what was recorded on medical records as given in the hospital.' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:43:05
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (ex. 325mg). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:45:40
User entered '324'	Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
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	11 Dec 2020 19:57:13
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 19:57:13
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 19:57:05
User entered empty.	Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User entered empty.	System	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User entered empty.	System	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:21:28
User entered empty.	System	11 Dec 2020 19:57:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE SODIUM, PRODUCTSYNONYM: CEFRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 20:01:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 20:01:50
Data point term sent to Coder	System	11 Dec 2020 20:01:40
Data point term sent to Coder	System	11 Dec 2020 20:00:37
User entered 'ceftriaxone'	Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'SUSPECTED PNEUMONIA associated with AE #4' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:33
User entered 'suspected pneumonia'	Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'g (g)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '18 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User entered '1'	System	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User entered '1'	System	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:25
User entered '804 (804)'	System	11 Dec 2020 19:59:59

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Dec 2020 20:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Dec 2020 20:22:57
Data point term sent to Coder	System	11 Dec 2020 20:01:40
User entered 'digoxin'	Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'atrial flutter/fibrillation associated with AE #5'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '500'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'ug (ug)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User entered empty.	System	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User entered empty.	System	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:35
User entered empty.	System	11 Dec 2020 20:01:12

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Dec 2020 20:44:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Dec 2020 20:44:49
Data point term sent to Coder	System	11 Dec 2020 20:05:44
User entered 'famotidine'	Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'to prevent GI upset related to medication administration - associated with AE #4'	Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'twice daily (BID)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User entered '2'	System	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User entered '1'	System	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:23:08
User entered '804 (804)'	System	11 Dec 2020 20:04:48

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:23
Data point term sent to Coder	System	11 Dec 2020 20:10:49
User entered 'lasix'	Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (ex. Hypertension). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:12:20
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (ex. Hypertension). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'This medication is associated with AE #4 hospitalization r/t edema associated with cardiovascular history.' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:46:51
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (ex. Hypertension). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:46:01
User entered 'diuretic - associated with AE #4'	Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '60'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'as needed (PRN)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '19 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User entered empty.	System	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User entered empty.	System	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:50
User entered empty.	System	11 Dec 2020 20:09:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:30:23
Data point term sent to Coder User entered 'lasix'	System Hollie Macenczak (b) (4)	11 Dec 2020 20:12:52 11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (ex. Hypertension). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:12:44
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (ex. Hypertension). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'This medication is associated with AE #4 hospitalization r/t edema associated with cardiovascular history.' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:47:01
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (ex. Hypertension). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:48:52
User entered 'diuretic - associated with AE #4'	Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '40'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User entered '1'	System	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User entered '1'	System	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:54
User entered '804 (804)'	System	11 Dec 2020 20:12:05

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Dec 2020 00:31:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 00:31:52
Data point term sent to Coder	System	11 Dec 2020 20:14:53
User entered 'heparin drip'	Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:14:48
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'updated' (Site from DM).	Hollie Macenczak (b) (4)	19 Feb 2021 17:45:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	19 Feb 2021 17:45:36
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:48:22
User entered 'No (N)'	Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'clot prevention associated with AE #5'	Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '18.4'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'units/kg/hour'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'continuous infusion'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '19 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User entered empty.	System	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User entered empty.	System	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:23
User entered empty.	System	11 Dec 2020 20:14:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 21:26:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:26:54
Data point term sent to Coder	System	11 Dec 2020 20:16:55
User entered 'hydralazine'	Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'hypertension associated with AE #4'	Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '25'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'three times daily (TID)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User entered '3'	System	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User entered '1'	System	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:28
User entered '804 (804)'	System	11 Dec 2020 20:16:22

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: OTHER ANTIHYPERTENSIVES, ATC: ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 02:02:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:02:47
Data point term sent to Coder	System	11 Dec 2020 20:33:09
Data point term sent to Coder	System	11 Dec 2020 20:32:08
User entered 'magnesium sulfate'	Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'HYPERTENSION associated with AE #4' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:31
User entered 'hypertension'	Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '50'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'ml/hr'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'continuous infusion'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '18 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User entered empty.	System	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User entered empty.	System	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:33
User entered empty.	System	11 Dec 2020 20:32:03

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Dec 2020 15:22:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 15:22:08
Data point term sent to Coder	System	11 Dec 2020 20:37:13
User entered 'metoprolol'	Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'hypertension associated with AE #4'	Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '12.5'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User entered empty.	System	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User entered empty.	System	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:39
User entered empty.	System	11 Dec 2020 20:36:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Dec 2020 15:22:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 15:22:49
Data point term sent to Coder	System	11 Dec 2020 20:38:14
User entered 'metoprolol'	Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'hypertension associated with AE #4'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '2.5'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User entered empty.	System	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User entered empty.	System	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:25:45
User entered empty.	System	11 Dec 2020 20:38:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:41:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:41:44
Data point term sent to Coder	System	11 Dec 2020 20:55:27
User entered 'Nitroglycerin'	Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'chest pain related to ACS associated with AE #4'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5-10'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mcg/min'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	11 Dec 2020 20:55:39
User entered 'continuous infusion' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	11 Dec 2020 20:55:39
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	11 Dec 2020 20:55:11
User entered empty.	Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User entered empty.	System	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User entered empty.	System	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:30
User entered empty.	System	11 Dec 2020 20:55:11

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Dec 2020 21:49:01
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 Dec 2020 21:49:01
Data point term sent to Coder	System	11 Dec 2020 20:59:29
User entered 'odansetron'	Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'nausea - associated with AE #4'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '4'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User entered empty.	System	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User entered empty.	System	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:40
User entered empty.	System	11 Dec 2020 20:58:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Dec 2020 00:32:21
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 00:32:21
Data point term sent to Coder	System	11 Dec 2020 21:01:30
User entered 'potassium chloride'	Hollie Macenczak (b) (4) (b) (4) (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'hypokalemia related to lasix administration associated with AE #4'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '40'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mEq'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'as needed (PRN)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '18 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '20 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User entered empty.	System	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User entered empty.	System	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:44
User entered empty.	System	11 Dec 2020 21:01:25

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
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)	19 Jan 2021 17:18:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 17:18:07
Data point term sent to Coder	System	19 Jan 2021 17:17:17
User entered 'Amiodarone'	(b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Atrial Flutter'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '200'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 17:16:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Feb 2021 13:50:28
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 Feb 2021 13:50:28
Data point term sent to Coder	System	29 Jan 2021 20:05:03
User entered 'quetiapine'	Hollie Macenczak (b) (4) 	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'bipoloar disorder'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '200'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once daily (QD)'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 20:04:48
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	29 Jan 2021 20:04:48
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:04:36
User entered empty.	Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un UNK 2018'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 20:04:53
User entered 'No (N)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	29 Jan 2021 20:04:53
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:04:36
User entered empty.	Hollie Macenczak (b) (4)	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User entered '1'	System	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User entered '1'	System	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:26:53
User entered '804 (804)'	System	29 Jan 2021 20:04:36

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: EPTIFIBATIDE, PRODUCTSYNONYM: INTEGRILIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 21:03:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 21:03:32
Data point term sent to Coder	System	02 Feb 2021 21:02:33
User entered 'Integrilin'	Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'myocardial infarction'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'unknown'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 21:02:42
User entered 'Other (OTHER)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	02 Feb 2021 21:02:42
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:01:46
User entered empty.	Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'unknown' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:02:42
User entered empty.	Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'other (OTHER)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'continuous drip'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
User entered '31 Oct 2020' reason for change: Data Entry Error	System	02 Feb 2021 21:04:32
User opened query 'End date is prior to start date. Please correct.' (Site from System).	Hollie Macenczak (b) (4)	02 Feb 2021 21:04:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).		
User entered 'UN UNK 2020' reason for change: Data Entry Error	System	02 Feb 2021 21:03:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Feb 2021 21:03:56
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	02 Feb 2021 21:03:56
User entered 'UN UNK unk' (non-conformant).	Hollie Macenczak (b) (4)	02 Feb 2021 21:03:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	02 Feb 2021 21:02:42
User entered 'UN UNK unk' (non-conformant).	System	02 Feb 2021 21:02:42
User opened query 'End date is prior to start date. Please correct.' (Site from System).	Hollie Macenczak (b) (4)	02 Feb 2021 21:02:42
User entered 'un Oct 2020'		
	System	02 Feb 2021 21:01:46
	Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User entered empty.	System	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User entered empty.	System	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:24:38
User entered empty.	System	02 Feb 2021 21:01:46

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:45:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:45:36
Data point term sent to Coder Coding entries removed.	System Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:55:26 05 Apr 2021 17:55:23
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:25:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:25:01
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	04 Mar 2021 17:08:04 04 Mar 2021 17:07:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 23:42:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 23:42:52
Data point term sent to Coder User entered 'LASIX'	System Hollie Macenczak (b) (4)	12 Feb 2021 23:42:00 12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:23:24
User closed query 'Per DM CLR-RQ: Thank you for the update. However, note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:52:09
Query 'Per DM CLR-RQ: Thank you for the update. However, note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Updated to match correct AE' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:55:32
Signature has been broken.	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:55:23
User entered 'ACUTE ON CHRONIC SYSTOLIC HEART FAILURE' reason for change: Per Query Resolution	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 17:55:23
User opened query 'Per DM CLR-RQ: Thank you for the update. However, note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:59:10
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	24 Mar 2021 01:46:09
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:06:19

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'HEART FAILURE AND RESULTANT PERIPHERAL AND PULMONARY EDEMA HE SUFFERED IS THE INDICATION FOR THIS MEDICATION.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:08:17
User entered 'HEART FAILURE' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Mar 2021 17:07:42
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:40:03
User entered 'diuretic'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '20'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'mg (mg)'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'once daily (QD)'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Oral (ORAL)'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '3 Feb 2021'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered '0'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
	(b) (4)	
User entered 'No (N)'	Hollie Macenczak (b) (4)	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Feb 2021 23:41:41

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 16:33:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:33:42
Data point term sent to Coder User entered 'Botox'	System (b) (4), (b) (6)	03 Mar 2021 16:18:29 03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:52:18
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Botox in this case was used for cosmetic purposes, not as a prophylaxis.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	05 Apr 2021 18:01:26
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:59:22
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Cosmetic'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Units'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un May 2017'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'un May 2017'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User entered empty.	System	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User entered empty.	System	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:50:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:22:05
User entered empty.	System	03 Mar 2021 16:17:52

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:50:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:33:16
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:54:07

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'CARDIAC CATHETERIZATION WITH ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTION'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:50:35

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:14
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '17 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:42:15

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:14
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'echocardiogram'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:42:15

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:14
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:42:15

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:14
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:42:15

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '19 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:42:52

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'cardiovascular MRI'	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:42:52

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	11 Dec 2020 21:43:13
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	11 Dec 2020 21:42:52
User entered 'Adverse Event (AE)'	Hollie Macenczak (b) (4)	11 Dec 2020 21:42:52

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:17
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	11 Dec 2020 21:43:13
User entered 'incomplete due to claustrophobia'	Hollie Macenczak (b) (4)	11 Dec 2020 21:42:52

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:31

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'ELECTROCARDIOGRAM'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:31

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:31

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:19
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:31

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:22
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	(b) (4) System	22 Jan 2021 19:08:15
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:08:15
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	22 Jan 2021 19:07:59
User entered '6 Nov 2019'	(b) (4), (b) (6)	22 Jan 2021 19:07:59

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:22
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'ECHOCARDIOGRAM'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:59

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:22
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:59

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:22
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:59

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:29
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 19:28:13

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:29
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Electrocardiogram' reason for change:	(b) (4)	
Data Entry Error	Hollie Macenczak (b) (4)	29 Jan 2021 19:28:42
User entered 'EKG'	Hollie Macenczak (b) (4)	29 Jan 2021 19:28:13

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:29
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 19:28:13

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:29
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 19:28:13

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:31
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 19:32:00

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:31
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Chest xray'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 19:32:00

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:31
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 19:32:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:31
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	29 Jan 2021 19:32:00

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '29 Oct 2020'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:15:44

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'standard of care blood work for chest pain protocol'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:15:44

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:15:44

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:35
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	02 Feb 2021 22:15:44

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:50:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:41
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '16 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	19 Feb 2021 17:06:19

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:50:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:41
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'blood cultures'	(b) (4) Hollie Macenczak (b) (4)	19 Feb 2021 17:06:19

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:50:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:41
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'Adverse Event (AE)'	(b) (4) Hollie Macenczak (b) (4)	19 Feb 2021 17:06:19

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:50:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:33:41
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	19 Feb 2021 17:06:19

US3482284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:50:35

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '04 Dec 2020'	(b) (4) Sarah Bechnak (b) (4)	14 Dec 2020 17:23:55
	(b) (4)	

US3482284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:50:35

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:33
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'SAE (specify) (SAE)'	(b) (4) Sarah Bechnak (b) (4)	14 Dec 2020 17:23:55

US3482284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:50:35

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:33
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Nadine Rouphael (b) (4)	24 Mar 2021 08:13:20 24 Mar 2021 01:46:09
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'updated to include # and AE logline number' (Site from DM). User entered '#1 #2 #3 #4 #5 #6' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	23 Mar 2021 20:20:08
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:39:34
Query 'Per CDM re-query: Please enter only SAE and SAE record number without additional information in this field (eg: SAE #1) and please record only the main SAE responsible for dosing discontinuation. Thank you ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:39:09
User closed query 'Per CDM: Please enter SAE record number in this field (i.e. SAE #1 etc) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 10:33:19

US3482284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:50:35

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Please enter only SAE and SAE record number without additional information in this field (eg: SAE #1) and please record only the main SAE responsible for dosing discontinuation. Thank you ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 10:33:16
Query 'Per CDM re-query: Please enter only SAE and SAE record number without additional information in this field and please record only the main SAE responsible for dosing discontinuation. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 10:32:36
User opened query 'Per CDM re-query: Please enter only SAE and SAE record number without additional information in this field and please record only the main SAE responsible for dosing discontinuation. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 10:32:32
Query 'Per CDM: Please enter SAE record number in this field (i.e. SAE #1 etc) as appropriate. ' answered with 'updated' (Site from DM).	Hollie Macenczak (b) (4)	29 Jan 2021 20:10:56
User entered 'NOT ELIGIBLE DUE TO UNSTABLE CARDIAC STATE (see SAE numbers 1-6).' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	29 Jan 2021 20:10:49
User opened query 'Per CDM: Please enter SAE record number in this field (i.e. SAE #1 etc) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:30:47
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	14 Dec 2020 17:24:37
User entered 'NOT ELIGIBLE DUE TO UNSTABLE CARDIAC STATE' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	14 Dec 2020 17:24:37
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	14 Dec 2020 17:23:55
User entered empty.	Sarah Bechnak (b) (4)	14 Dec 2020 17:23:55

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
User entered '02/Nov/2020 16:18'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
User entered '09/Nov/2020 19:50'	System	09 Nov 2020 19:50:36

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 19:50:36

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:16
User entered '11/Nov/2020 13:41'	System	11 Nov 2020 13:41:17

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:52:28
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 13:41:17

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '12/Nov/2020 15:06'	System	12 Nov 2020 15:06:28

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 14:34:22
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 15:06:28

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '17/Nov/2020 14:34'	System	17 Nov 2020 14:34:34

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 21:05:42
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 14:34:34

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '18/Nov/2020 21:05'	System	18 Nov 2020 21:05:54

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:46:55
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 21:05:54

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '02/Dec/2020 09:47'	System	02 Dec 2020 14:47:07

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 14:30:18
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 14:47:07

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '09/Dec/2020 09:30'	System	09 Dec 2020 14:30:52

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:34:45
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 14:30:52

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '11/Dec/2020 09:34'	System	11 Dec 2020 14:35:01

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 15:45:36
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 14:35:01

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '11/Dec/2020 10:46'	System	11 Dec 2020 15:46:08

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:00:29
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 15:46:08

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:00:29
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 15:46:08

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '14/Dec/2020 09:01'	System	14 Dec 2020 14:01:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:03:18
User entered 'I'	(b) (4), (b) (6)	14 Dec 2020 14:01:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '23/Dec/2020 11:05'	System	23 Dec 2020 16:05:37

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:52:27
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 16:05:37

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '06/Jan/2021 14:52'	System	06 Jan 2021 14:52:41

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:30
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 14:52:41

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '25/Jan/2021 16:52'	System	25 Jan 2021 16:52:45

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:55:06
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 16:52:45

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '01/Feb/2021 10:55'	System	01 Feb 2021 15:55:22

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 19:17:33
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:55:34
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 15:55:22

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered '19/Feb/2021 14:00'	System	19 Feb 2021 19:00:46

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:02
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 19:17:33
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 19:00:46

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

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Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

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Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

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Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
	(b) (4)	
User entered 'Rouphael' reason for change: Data	Michele McCullough	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

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Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

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Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

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Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

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Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:50:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

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Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '17'	System	19 Feb 2021 20:03:19
User entered '16'	System	19 Feb 2021 19:00:46
User entered '15'	System	01 Feb 2021 15:55:22
User entered '14'	System	25 Jan 2021 16:52:45
User entered '13'	System	06 Jan 2021 14:52:41
User entered '12'	System	23 Dec 2020 16:05:37
User entered '11'	System	14 Dec 2020 14:01:29
User entered '10'	System	11 Dec 2020 15:46:08
User entered '9'	System	11 Dec 2020 14:35:01
User entered '8'	System	09 Dec 2020 14:30:52
User entered '7'	System	02 Dec 2020 14:47:07
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

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Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 17:50:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered '19/Feb/2021 15:03'	(b) (4) System	19 Feb 2021 20:03:19

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Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 17:50:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	24 Mar 2021 01:46:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:03:19