

US3302455 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:02:30

All time stamps listed in this document are displayed in GMT

US3302455

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

[Participant ID](#)

US3302455

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

US3302455

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	HYPERTENSION
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)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	DIABETES TYPE 2
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)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	HYPERCHOLESTEROLEMIA
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)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	BIO POLAR DISORDER (IN REMISSION)
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	CHRONIC KIDNEY DISEASE (STAGE 3)
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)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	HYPONATREMIA (SECONDARY TO KIDNEY DISEASE)
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)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	ALZHEIMER'S DISEASE
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)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	BACK PAIN (LOWER BACK)
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 (14)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	HEART MURMUR
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 (17)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	ONYCHOMYCOSIS (BILATERAL FEET/ INTERMITTENT)
Start date (dd MMM yyyy)	UN UNK 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 (20)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	OVERDOSE OF OPIATE AGONIST
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 (21)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	O2 DEPENDENT
Start date (dd MMM yyyy)	UN UNK 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 (22)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	RENAL INSUFFICIENCY (SECONDARY KIDNEY DISEASE)
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)	_____

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Condition	SLEEP APNEA (NO C-PAP)
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:46
Height (xxx.x)	64 in
Weight (xxx.x)	214 lb
BMI (xxx.x)	36.80982 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Date of assessment (dd MMM yyyy) 21 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:30:19

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 188872

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☒ No ☐

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:46
Temperature (xxx.x)	97.1 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

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)	21 SEP 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:08
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:30:19

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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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 11:38 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 11:38

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

US3302455

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	11:18 (24 HR)
Collection date and time (derived)	21 SEP 2020 11:18

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:16	21 SEP 2020 11:16
Nasopharyngeal Swab 2	No		

US3302455

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:04

PC Open Date & Time

21 SEP 2020 11:58

PC Close Date & Time

21 SEP 2020 14:28

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 SEP 2020 15:23

PC Close Date & Time

22 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

97.9 °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

22 SEP 2020 18:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

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 ☒

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 23 SEP 2020 17:38

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

27 SEP 2020 12:29

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:05

PC Open Date & Time

21 SEP 2020 11:58

PC Close Date & Time

21 SEP 2020 14:28

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 15:23

PC Close Date & Time

22 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

22 SEP 2020 18:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

23 SEP 2020 17:40

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

27 SEP 2020 12:29

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 12:06
PC Open Date & Time	21 SEP 2020 11:58
PC Close Date & Time	21 SEP 2020 14:28

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 15:23

PC Close Date & Time

22 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

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 ☒

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 18:19
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

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 ☒

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 17:40
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

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 ☒

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:30
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3302455

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	VISIT2

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

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)	19 OCT 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 09:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

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)	19 OCT 2020
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 10:13
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3302455

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

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) 19 OCT 2020

What was the treatment time? (00:00-23:59) 09:43 (24 HR)

Treatment Date and Time (derived) 19 OCT 2020 09:43

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

US3302455

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

09:19 (24 HR)

Collection date and time (derived)

19 OCT 2020 09:19

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Collection date (dd MMM yyyy)			19 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:17	19 OCT 2020 09:17
Nasopharyngeal Swab 2	No		

US3302455

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 10:04

PC Open Date & Time

19 OCT 2020 10:03

PC Close Date & Time

19 OCT 2020 12:33

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 19 OCT 2020 13:28

PC Close Date & Time 20 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

97.9 °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

20 OCT 2020 19:50

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

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 ☒

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 23 OCT 2020 11:17

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

24 OCT 2020 16:37

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

25 OCT 2020 15:12

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 10:05

PC Open Date & Time

19 OCT 2020 10:03

PC Close Date & Time

19 OCT 2020 12:33

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 OCT 2020 13:28

PC Close Date & Time

20 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

20 OCT 2020 19:50

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	23 OCT 2020 11:17
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

24 OCT 2020 16:37

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	25 OCT 2020 15:12
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

No ☒

Yes ☐

PC Time stamp	19 OCT 2020 10:05
PC Open Date & Time	19 OCT 2020 10:03
PC Close Date & Time	19 OCT 2020 12:33

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

19 OCT 2020 13:28

PC Close Date & Time

20 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 19:51
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

Yes ☐

PC Time stamp

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

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 ☒

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 11:18
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

Yes ☐

PC Time stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

120 of 2711

EAB) (1725)

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 16:38
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

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 ☒

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 15:13
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3302455

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	VISIT3

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	09:24 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 09:24
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302455

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3302455

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 NOV 2020
Collection time (00:00-23:59)	09:48 (24 HR)
Collection date and time (derived)	16 NOV 2020 09:48

US3302455

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:19

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 <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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	27 DEC 2020 23:59
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US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 <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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 14:56:47

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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	20 JAN 2021 06:27:57
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 JAN 2021 15:17:00
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

03 FEB 2021 11:59:04

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 <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 07:08:26
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 23:44:59
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

24 FEB 2021 17:43:14

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 23:00:58

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 MAR 2021 17:31:44
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

18 MAR 2021 20:28:49

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

24 MAR 2021 21:16:31

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 07:44:53
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

07 APR 2021 18:49:55

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 16:33:37

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 15:00:06

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 20:02:33

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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°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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Patient Cloud Open Date & Time	25 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 <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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 <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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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°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 ☐

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

16 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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="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"/>

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 NOV 2022 00:01
Patient Cloud Close Date & Time	27 NOV 2022 23:59

US3302455

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:02:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 23:01:21

US3302455

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:26:21

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:26:21

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 APR 2021
Time of assessment (00:00-23:59)	09:53 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 09:53
Temperature (xxx.x)	97.7 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)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302455

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

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.

US3302455

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 APR 2021
Collection time (00:00-23:59)	09:57 (24 HR)
Collection date and time (derived)	20 APR 2021 09:57

US3302455

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3302455

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:02:30

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3302455

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:02:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Height	
Weight	
BMI (xxx.x)	

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	09:41 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 09:41
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:28
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 09:52 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 09:52

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

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

09:25 (24 HR)

Collection date and time (derived)

14 JAN 2021 09:25

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	09:23
Collection Date and Time (derived)	14 JAN 2021 09:23

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

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

US3302455

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3302455

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

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)	11 FEB 2021
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 10:44
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

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)	11 FEB 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 11:20
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3302455

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 16:08:21

Generated On: 09 Jun 2021 17:02:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3302455

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 10:50

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

US3302455

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302455

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:30:18

Generated On: 09 Jun 2021 17:02:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302455

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:26:21

Generated On: 09 Jun 2021 17:02:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 18:26:21

Generated On: 09 Jun 2021 17:02:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 08:48
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:26:21

Generated On: 09 Jun 2021 17:02:30

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-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:26:21

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	08:50 (24 HR)
Collection date and time (derived)	11 MAR 2021 08:50

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Folder: Unscheduled 11 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Visit Date	11 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

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Folder: Unscheduled 11 Feb 2021

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 12:38:28

Generated On: 09 Jun 2021 17:02:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00-23:59)	10:46 (24 HR)
Collection date and time (derived)	11 FEB 2021 10:46

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 25 Mar 2021 18:26:21

Generated On: 09 Jun 2021 17:02:30

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) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

AEID	USA-US087-2021-MRNA-1273-P30 1000023
Adverse event	ACUTE CVA
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)	06 MAR 2021
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)	10 MAR 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	10 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

SUBJECT PRESENTED TO SITE
AND COMPLETED OL V3 AND
REPORTED HAVING BEEN
HOSPITALIZED FOR AN ACUTE
CVA. MEDICAL RECORD
RELEASE FORM COMPLETED
AND SENT VIA FAX. ONCE
RECORDS ARE
RECEIVED/REVIEWED, CON
MEDS LIST WILL BE UPDATED.
4/22/2021: MEDICAL RECORDS
REGARDING SAE HAS BEEN
RECEIVED/REVIEWED. ALL
CON MEDS, MEDICAL HISTORY,
AND AE'S LISTS UPDATED IN
SOURCE AND EDC. IRB WAS
UPDATED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

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) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (2)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication INDAPAMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 1.25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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 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 (3)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 1.2

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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 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 (4)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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 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 (5)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 0.1

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 (7)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication ATOVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPONATREMIA

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) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 35

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

Q 12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication COGENTIN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 (13)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)		06 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication CLOBESTASOL (0.05%)

Prophylaxis Yes ☐
No ☒

Indication ONYCHOMYCOSIS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 75

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	07 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (16)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication INADAPAMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 1.25

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 (16)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication MEMANTINE

Prophylaxis Yes ☐
No ☒

Indication ALZHEIMER'S DISEASE

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 (18)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication OLANZAPINE

Prophylaxis Yes ☐
No ☒

Indication BI-POLAR DISEASE

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 (19)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify LITERS

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

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 12:38:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
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 (21)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication PAROXETINE

Prophylaxis Yes ☐
No ☒

Indication MENOPAUSE

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	07 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 1.8

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (23)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication HYDRALAZINE

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 (23)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)		10 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (24)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication SODIUM CHLORIDE (0.9%
INFUSION)

Prophylaxis Yes ☐
No ☒

Indication CVA

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

CONTINUOUS

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) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication TUBERCULIN INJECTION

Prophylaxis Yes ☐
No ☒

Indication TB SKIN TEST

Dose per administration 5

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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	INTRADERMAL	
Start date (dd MMM yyyy)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication HEPARIN INJECTION

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 5,000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

Q 8 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	08 MAR 2021	
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 (29)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 30

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

Q 12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)		06 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 0-14

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

4 TIMES BEFORE MEALS AND
NIGHTLY

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) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 12:38:27

Generated On: 09 Jun 2021 17:02:30

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3302455

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 20:29:54

Generated On: 09 Jun 2021 17:02:30

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3302455

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:02:30

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3302455

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:30

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 ☐

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

SAEID	USA-US087-2021-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

SAEID	USA-US087-2021-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/MAR/2021 09:58
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

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

SAEID	USA-US087-2021-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/MAR/2021 13:59
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

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

SAEID	USA-US087-2021-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/APR/2021 05:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 17:27:18

Generated On: 09 Jun 2021 17:02:30

SAEID	USA-US087-2021-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/APR/2021 11:43
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

US3302455 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302455

Form: Participant Creation

Generated On: 09 Jun 2021 17:02:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User closed query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:28:35
Query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	23 Nov 2020 02:25:44
User opened query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:31:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:49:07
User entered 'US3302455'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 14:21:02

US3302455

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:49:23
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:17

US3302455

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:49:23
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 14:21:03

US3302455

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:49:23
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:17

US3302455

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'SCRN'	System	21 Sep 2020 15:42:17

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 14:21:06

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '67'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'YEARS'	System	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '67'	System	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered 'Female (F)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered 'l'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:33
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:30

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:51:57
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Sep 2020'	System	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2020'	System	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:51:57
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 16:22:05
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:51:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:51:57
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:51:57
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:51:57
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:52

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:51:57
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 14:21:03

US3302455

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'I'	System	21 Sep 2020 15:42:56

US3302455

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:02:30

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:52:38
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:42:56

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:02:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:25
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:00

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 15:59:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 15:59:42
Data point term sent to Coder	System	21 Sep 2020 15:58:56
User entered 'gerd'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'un Jun 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jun 2020'	System	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2020'	System	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:16

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
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) (6)	30 Oct 2020 09:59:53
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 17:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Oct 2020 17:12:41
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 and Con Meds are listed for Hypertension (HTN).' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 16:12:15
Data point term sent to Coder	System	29 Oct 2020 16:10:33
Coding entries removed.	Brittany Belcher (b) (4)	29 Oct 2020 16:10:11
User entered 'Hypertension' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 16:10:11

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Condition](#)

Audit	User	Time (GMT)
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)	16 Oct 2020 06:21:22
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 15:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Sep 2020 15:59:43
Data point term sent to Coder	System	21 Sep 2020 15:58:57
User entered 'htn'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:31:24
User closed query 'Per source the start date was adjusted from 00-000-2020 to 00-000-2019. Please review the source and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:31:12
Query 'Per source the start date was adjusted from 00-000-2020 to 00-000-2019. Please review the source and update accordingly. ' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	23 Nov 2020 03:43:39
DataPoint Un-verified.	brittany cooksey (b) (4)	23 Nov 2020 03:43:31
User entered 'UN UNK 2019' reason for change: Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 03:43:31
User opened query 'Per source the start date was adjusted from 00-000-2020 to 00-000-2019. Please review the source and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:08:10
Query 'Per source the start date is was adjusted from 00-000-2020 to 00-000-2019. Please review the source and update accordingly. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:07:17
User opened query 'Per source the start date is was adjusted from 00-000-2020 to 00-000-2019. Please review the source and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:06:26
Query 'Per source the start date was adjusted from 00-MAY-2020 to 00-000-2019. Please review the source and update accordingly. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:06:03

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User opened query 'Per source the start date was adjusted from 00-MAY-2020 to 00-000-2019. Please review the source and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:04:58
Query 'Per source the start date is was adjusted from 00-000-2020 to 00-000-2019. Please review the source and update accordingly. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:04:12
User opened query 'Per source the start date is was adjusted from 00-000-2020 to 00-000-2019. Please review the source and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:03:34
User entered 'un May 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:26

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2019'	System	23 Nov 2020 03:43:31
User entered 'May 2020'	System	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2019'	System	23 Nov 2020 03:43:31
User entered '2020'	System	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:26

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
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) (6)	30 Oct 2020 09:59:50
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 'Con Meds listed for Diabetes Type 2' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 16:12:53
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)	16 Oct 2020 06:23:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 15:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 15:59:43
Data point term sent to Coder	System	21 Sep 2020 15:58:56

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Condition](#)

Audit	User	Time (GMT)
User entered 'diabetes type 2'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2019'	System	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2019'	System	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:41

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 15:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 15:59:43
Data point term sent to Coder	System	21 Sep 2020 15:58:56
User entered 'hypercholesterolemia'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2019'	System	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2019'	System	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	21 Sep 2020 15:58:54

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:43:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:43:28
Data point term sent to Coder	System	09 Oct 2020 12:42:04
User entered 'POST MENOPAUSAL'	marsha gossett (b) (4)	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'UN UNK 2015'	marsha gossett (b) (4)	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	marsha gossett (b) (4)	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered 'Yes (Y)'	marsha gossett (b) (4)	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered empty.	marsha gossett (b) (4)	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:34
User entered '0'	marsha gossett (b) (4)	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2015'	System	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2015'	System	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	09 Oct 2020 12:41:42

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:03
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)	23 Apr 2021 05:15:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:15:47
Data point term sent to Coder	System	22 Apr 2021 19:55:36
User entered 'Bio Polar Disorder (In Remission)'	Kendal Nelson (b) (4)	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Apr 2021 19:55:39
User entered 'UN UNK 1999' reason for change: New Information	Kendal Nelson (b) (4)	22 Apr 2021 19:55:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	22 Apr 2021 19:55:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Apr 2021 19:55:07
User entered '00 UNK 1999' (non-conformant).	Kendal Nelson (b) (4)	22 Apr 2021 19:55:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	22 Apr 2021 19:54:57
User entered '00 1999' (non-conformant).	Kendal Nelson (b) (4)	22 Apr 2021 19:54:57
	(b) (4)	

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:07
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:10
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:12
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:14
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 1999'	System	22 Apr 2021 19:55:39
User entered empty.	System	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '1999'	System	22 Apr 2021 19:55:39
User entered empty.	System	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:54:57

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:32
User coded data point as SOC: Renal and urinary disorders, HLG: 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)	23 Apr 2021 05:22:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:22:53
Data point term sent to Coder	System	22 Apr 2021 19:57:39
User entered 'CHRONIC KIDNEY DISEASE (STAGE 3)'	Kendal Nelson (b) (4)	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:35
User entered 'UN UNK 2019'	Kendal Nelson (b) (4)	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:36
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:38
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:40
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:42
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2019'	System	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2019'	System	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:56:41

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:19
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 06:50:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 06:50:44
Data point term sent to Coder	System	22 Apr 2021 19:57:38
User entered 'Hyponatremia (secondary to Kidney Disease)'	Kendal Nelson (b) (4)	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:20
User entered 'UN UNK 2019'	Kendal Nelson (b) (4)	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:22
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:24
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:27
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:29
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2019'	System	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2019'	System	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:57:24

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:50
User coded data point as SOC: Nervous system disorders, HLG: Mental impairment disorders, HLT: Alzheimer's disease (incl subtypes), PT: Dementia Alzheimer's type, LLT: Alzheimer's disease - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 19:59:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 19:59:03
Data point term sent to Coder	System	22 Apr 2021 19:58:41
User entered 'ALZHEIMER'S DISEASE'	Kendal Nelson (b) (4)	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:52
User entered 'UN UNK 2019'	Kendal Nelson (b) (4)	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:54
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:56
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:58
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:03
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2019'	System	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2019'	System	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:58:37

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:17
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia, unspecified - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 00:11:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 00:11:01
Data point term sent to Coder	System	22 Apr 2021 19:59:43
User entered 'ANEMIA (UNSPECIFIED)'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:21
User entered 'UN UNK 2005'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:23
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:25
User entered 'No (N)' reason for change: New Information	Kendal Nelson (b) (4)	22 Apr 2021 20:02:39
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:28
User entered 'UN UNK 2005' reason for change: New Information	Kendal Nelson (b) (4)	22 Apr 2021 20:02:39
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:31
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2005'	System	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2005'	System	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2005'	System	22 Apr 2021 20:02:39
User entered empty.	System	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2005'	System	22 Apr 2021 20:02:39
User entered empty.	System	22 Apr 2021 19:59:06

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:55
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:00:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:00:04
Data point term sent to Coder	System	22 Apr 2021 19:59:43
User entered 'ANXIETY'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:08:58
User entered 'UN UNK 1999'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:00
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:02
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:05
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:07
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 1999'	System	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '1999'	System	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:59:33

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:29
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:02:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:02:09
Data point term sent to Coder	System	22 Apr 2021 20:00:44
User entered 'DEPRESSION'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:32
User entered 'UN UNK 1999'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:34
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:35
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:37
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:39
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 1999'	System	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '1999'	System	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 19:59:55

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 02:58:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 02:58:45
Data point term sent to Coder	System	22 Apr 2021 20:00:47
User entered 'Back Pain (Lower Back)'	Kendal Nelson (b) (4)	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:54
User entered 'UN UNK 2010'	Kendal Nelson (b) (4)	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:55
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:09:58
User entered 'No (N)' reason for change: New Information	Kendal Nelson (b) (4)	22 Apr 2021 20:02:16
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:00
User entered 'UN UNK 2010' reason for change: New Information	Kendal Nelson (b) (4)	22 Apr 2021 20:02:16
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:03
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2010'	System	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2010'	System	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2010'	System	22 Apr 2021 20:02:16
User entered empty.	System	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2010'	System	22 Apr 2021 20:02:16
User entered empty.	System	22 Apr 2021 20:00:30

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:18
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Hyperkeratoses, PT: Hyperkeratosis, LLT: Foot callus - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:15:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:15:49
Data point term sent to Coder	System	22 Apr 2021 20:01:51
User entered 'Callus of Foot (Right)'	Kendal Nelson (b) (4)	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:26
User entered 'UN UNK 2018'	Kendal Nelson (b) (4)	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:28
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:33
User entered 'No (N)'	Kendal Nelson (b) (4)	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Apr 2021 20:01:53
User entered 'UN UNK 2018' reason for change: New Information	Kendal Nelson (b) (4)	22 Apr 2021 20:01:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Apr 2021 20:01:45
User entered 'UN UNK ' (non-conformant).	Kendal Nelson (b) (4)	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:38
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2018'	System	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2018'	System	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2018'	System	22 Apr 2021 20:01:53
User entered empty.	System	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2018'	System	22 Apr 2021 20:01:53
User entered empty.	System	22 Apr 2021 20:01:45

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 20:04:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 20:04:59
Data point term sent to Coder	System	22 Apr 2021 20:04:03
User entered 'COPD'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:53
User entered 'UN UNK 2000'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:57
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:00
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:02
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:09
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2000'	System	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2000'	System	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:03:20

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:44
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.	Coder Import (b) (4)	22 Apr 2021 20:04:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:04:59
Data point term sent to Coder	System	22 Apr 2021 20:04:03
User entered 'HEART MURMUR'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:47
User entered 'UN UNK 2018'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:49
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:51
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:53
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:55
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2018'	System	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2018'	System	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:03:52

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:06:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:06:10
Data point term sent to Coder	System	22 Apr 2021 20:05:04
User entered 'HIATAL HERNIA'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:25
User entered 'UN UNK 1997'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:27
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:29
User entered 'No (N)'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:32
User entered 'UN UNK 1997'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:34
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 1997'	System	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '1997'	System	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 1997'	System	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '1997'	System	22 Apr 2021 20:04:24

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:43
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)	22 Apr 2021 20:06:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:06:10
Data point term sent to Coder	System	22 Apr 2021 20:05:04
User entered 'INSOMNIA'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:44
User entered 'UN UNK 2015'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:47
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:48
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:50
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:52
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2015'	System	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2015'	System	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:04:53

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:39
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:08:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:08:43
Data point term sent to Coder	System	22 Apr 2021 20:06:06
User entered 'Onychomycosis (Bilateral Feet/ Intermittent)'	Kendal Nelson (b) (4)	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:41
User entered 'UN UNK 2020'	Kendal Nelson (b) (4)	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:45
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:47
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:48
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:50
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2020'	System	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2020'	System	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:05:19

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:03
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Overdoses and underdoses NEC, HLT: Overdoses NEC, PT: Overdose, LLT: Drug overdose - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 11:50:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 11:50:49
Data point term sent to Coder	System	22 Apr 2021 20:07:07
User entered 'Overdose of Opiate Agonist'	Kendal Nelson (b) (4)	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:04
User entered 'UN UNK 2010'	Kendal Nelson (b) (4)	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:06
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:08
User entered 'No (N)'	Kendal Nelson (b) (4)	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:10
User entered 'UN UNK 2010'	Kendal Nelson (b) (4)	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:11
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2010'	System	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2010'	System	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2010'	System	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2010'	System	22 Apr 2021 20:06:22

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:33
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Dependence on oxygen therapy, LLT: Dependence on oxygen therapy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:07:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:07:53
Data point term sent to Coder	System	22 Apr 2021 20:08:08
User entered 'O2 Dependent'	Kendal Nelson (b) (4)	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:35
User entered 'UN UNK 2020'	Kendal Nelson (b) (4)	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:37
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:39
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:40
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:42
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2020'	System	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2020'	System	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:07:46

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:50
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal failure, LLT: Renal insufficiency - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:20:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 07:20:43
Data point term sent to Coder	System	22 Apr 2021 20:09:10
User entered 'Renal Insufficiency (Secondary Kidney Disease)'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:53
User entered 'UN UNK 2019'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:55
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:57
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:01
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2019'	System	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2019'	System	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:08:20

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 07:21:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 07:21:47
Data point term sent to Coder	System	22 Apr 2021 20:09:10
User entered 'Sleep Apnea (No C-PAP)'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:17
User entered 'UN UNK 2003'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:19
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:21
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:22
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:24
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2003'	System	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2003'	System	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:08:50

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:33
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)	22 Apr 2021 20:10:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 20:10:08
Data point term sent to Coder	System	22 Apr 2021 20:09:12
User entered 'Vitamin D Deficiency'	Kendal Nelson (b) (4)	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:36
User entered 'UN UNK 2005'	Kendal Nelson (b) (4)	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:38
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:39
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:41
User entered empty.	Kendal Nelson (b) (4)	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:42
User entered '0'	Kendal Nelson (b) (4)	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'Jan 2005'	System	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '2005'	System	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:02:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:50:32
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:58
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 11:52:14
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered empty.	System	22 Apr 2021 20:09:11

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered '10:46'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '21 Sep 2020 10:46'	System	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered '64' in	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52
DataPoint set to visible.	System	21 Sep 2020 15:42:56

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered '214' lb	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52
DataPoint set to visible.	System	21 Sep 2020 15:42:56

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered '36.80982'	System	21 Sep 2020 15:59:52
DataPoint set to visible.	System	21 Sep 2020 15:42:56

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'kg/m2'	System	21 Sep 2020 15:59:52
DataPoint set to visible.	System	21 Sep 2020 15:42:56

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 06:53:48
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	05 Oct 2020 17:16:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 17:16:23
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:13:35
User entered '97.1' F	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:16:23
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:16:23
User entered '79'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'bpm'	System	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:16:23
User entered '18'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'breaths/min'	System	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:16:23
User entered '144'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'mmHg'	System	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:09:42
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:16:23
User entered '84'	(b) (4)	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User entered 'mmHg'	System	21 Sep 2020 15:59:52

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05

US3302455

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05

US3302455

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:27
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:57

US3302455

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:27
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:59:57

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:37:35
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'ADDED' (Site from DM).	marsha gossett (b) (4)	09 Oct 2020 12:40:43
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 10:45:07
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User closed query 'Per CDM-If No, what is the reason? is recorded as 'Post-menopausal',however no data is entered in the field 'If Post-menopausal, date of last menstruation'. Kindly consider to update data accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:51:31
Query 'Per CDM-If No, what is the reason? is recorded as 'Post-menopausal',however no data is entered in the field 'If Post-menopausal, date of last menstruation'. Kindly consider to update data accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	15 Oct 2020 14:49:18
User entered 'un UNK 2015' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Oct 2020 14:49:09
User opened query 'Per CDM-If No, what is the reason? is recorded as 'Post-menopausal',however no data is entered in the field 'If Post-menopausal, date of last menstruation'. Kindly consider to update data accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:38:58
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:30

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:24
User entered '0' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Oct 2020 14:49:09
User entered '1'	Brittany Belcher (b) (4)	21 Sep 2020 16:00:22

US3302455

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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[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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered '0' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	03 Nov 2020 19:30:47
User entered '1'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

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)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

US3302455

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 19:30:47
User entered '0'	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered '0'	(b) (4) Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:29:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:37
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:43:52

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:17:49
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:44:08

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:17:49
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:44:08

US3302455

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:17:49
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	21 Sep 2020 15:44:08

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'VISIT1'	System	21 Sep 2020 15:44:08

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 15:21:14

US3302455

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered '188872'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 15:21:14

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 15:21:14

US3302455

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:45:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:45:47

US3302455

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:45:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:45:47

US3302455

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 15:45:47

US3302455

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:30

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:18:32
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:08:07
DataPoint set to visible.	System	23 Oct 2020 16:22:05

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 20:58:38
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	05 Oct 2020 17:12:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 17:12:53
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 19:11:00
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:12:53
User entered empty.	(b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 20:58:38
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	05 Oct 2020 17:12:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 17:12:53
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 19:11:00
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:12:53
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User closed query 'Per CDM: According to CCGs pages 15-16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", the expected vital signs data (except Height and Weight) should be recorded under Visit 1 Day 1 section of the eCRF. Please refer the CCGs for more information and update as needed. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 20:58:41
Query 'Per CDM: According to CCGs pages 15-16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", the expected vital signs data (except Height and Weight) should be recorded under Visit 1 Day 1 section of the eCRF. Please refer the CCGs for more information and update as needed. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 17:15:11
User opened query 'Per CDM: According to CCGs pages 15-16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", the expected vital signs data (except Height and Weight) should be recorded under Visit 1 Day 1 section of the eCRF. Please refer the CCGs for more information and update as needed. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 19:11:13
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '21 Sep 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '10:46' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered '21 Sep 2020 10:46'	System	05 Oct 2020 17:14:08
User entered empty.	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '97.1' F reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:41:14
DataPoint Un-verified.	brittany cooksey (b) (4)	23 Nov 2020 02:08:02
User entered 'Oral (Oral)' reason for change: Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 02:08:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered 'Other (Other)' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:41:17
User closed query 'Per source the route of measurement is documented as oral. Kindly review the source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:41:10
Query 'Per source the route of measurement is documented as oral. Kindly review the source and update accordingly.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	23 Nov 2020 02:08:26
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 02:08:02
User opened query 'Per source the route of measurement is documented as oral. Kindly review the source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:21:24
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:21:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered 'Temporal' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '79' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'bpm'	System	05 Oct 2020 17:14:08
User entered empty.	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '18' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'breaths/min'	System	05 Oct 2020 17:14:08
User entered empty.	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '144' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'mmHg'	System	05 Oct 2020 17:14:08
User entered empty.	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '84' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:14:08
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'mmHg'	System	05 Oct 2020 17:14:08
User entered empty.	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 20:58:38
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	05 Oct 2020 17:12:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 17:12:53
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 19:11:00
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 17:12:53
User entered empty.	(b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '12:08'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered '21 Sep 2020 12:08'	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '97.1' F	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '68'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'bpm'	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '18'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'breaths/min'	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '155'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'mmHg'	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:20:48
User entered '89'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'mmHg'	System	21 Sep 2020 18:46:31

US3302455

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:22:28
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:37

US3302455

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:22:28
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 18:46:37

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:43
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:43
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:46:11

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:43
User entered empty.	Brittany Belcher (b) (4)	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:43
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:43
User entered '11:38'	Brittany Belcher (b) (4)	21 Sep 2020 15:46:11

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered '21 Sep 2020 11:38'	System	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:43
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:43
User entered 'ONCE'	System	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 15:46:11

US3302455

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:55
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:48

US3302455

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:55
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:48

US3302455

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:55
User entered '11:18'	Brittany Belcher (b) (4)	21 Sep 2020 18:46:48

US3302455

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered '21 Sep 2020 11:18'	System	21 Sep 2020 18:46:48

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:08
User entered '21 Sep 2020'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:08
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:08
User entered '11:16'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered '21 Sep 2020 11:16'	System	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:08
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 17:42:34
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:08
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 17:42:34
User entered '11:16'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered empty.	System	20 Oct 2020 17:42:34
User entered '21 Sep 2020 11:16'	System	21 Sep 2020 18:47:02

US3302455

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:24
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Sep 2020 18:47:06

US3302455

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'I'	System	21 Sep 2020 18:47:06

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:04:13', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '2f7d51f5-5e24-44e9-ad5f-4e2a45443a76' User entered 'Yes (Y)'	System	21 Sep 2020 16:18:27
	System	21 Sep 2020 16:18:27

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:04:18', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '2f7d51f5-5e24-44e9-ad5f-4e2a45443a76' User entered '97.1'	System	21 Sep 2020 16:18:27
	System	21 Sep 2020 16:18:27

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:04:27', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '2f7d51f5-5e24-44e9-ad5f-4e2a45443a76'	System	21 Sep 2020 16:18:27
User entered 'No (N)'	System	21 Sep 2020 16:18:27

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:04:30', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '2f7d51f5-5e24-44e9-ad5f-4e2a45443a76'	System	21 Sep 2020 16:18:27
User entered '21 Sep 2020 12:04'	System	21 Sep 2020 16:18:27

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 11:58'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 14:28'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 15:23'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 2'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:30', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '15b7e3a2-9088-4d24-9618-6cb51e9e6e0e' User entered 'Yes (Y)'	System	22 Sep 2020 22:18:47
	System	22 Sep 2020 22:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:36', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '15b7e3a2-9088-4d24-9618-6cb51e9e6e0e' User entered '97.9'	System	22 Sep 2020 22:18:47
	System	22 Sep 2020 22:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:40', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '15b7e3a2-9088-4d24-9618-6cb51e9e6e0e' User entered 'No (N)'	System	22 Sep 2020 22:18:47
	System	22 Sep 2020 22:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:43', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '15b7e3a2-9088-4d24-9618-6cb51e9e6e0e' User entered '22 Sep 2020 18:18'	System	22 Sep 2020 22:18:47
	System	22 Sep 2020 22:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 3'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:38:20', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb00a3e5-6369-45dc-b695-9c54fbedc140' User entered 'No (N)'	System	23 Sep 2020 21:38:52
	System	23 Sep 2020 21:38:52

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:38:27', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb00a3e5-6369-45dc-b695-9c54fbedc140'	System	23 Sep 2020 21:38:52
User entered 'No (N)'	System	23 Sep 2020 21:38:52

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:38:32', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb00a3e5-6369-45dc-b695-9c54fbedc140' User entered '23 Sep 2020 17:38'	System	23 Sep 2020 21:38:52
	System	23 Sep 2020 21:38:52

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 4'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 5'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 6'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 7'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:03', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'f5413a78-ab43-474f-9fa9-9cd0fa579d83' User entered 'Yes (Y)'	System	27 Sep 2020 16:29:22
	System	27 Sep 2020 16:29:22

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:07', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'f5413a78-ab43-474f-9fa9-9cd0fa579d83' User entered '97.9'	System	27 Sep 2020 16:29:22
	System	27 Sep 2020 16:29:22

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:17', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'f5413a78-ab43-474f-9fa9-9cd0fa579d83'	System	27 Sep 2020 16:29:22
User entered 'No (N)'	System	27 Sep 2020 16:29:22

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:20', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'f5413a78-ab43-474f-9fa9-9cd0fa579d83'	System	27 Sep 2020 16:29:22
User entered '27 Sep 2020 12:29'	System	27 Sep 2020 16:29:22

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:04:38', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '591eb7aa-6661-4490-b656-72cf361df9eb' User entered 'None (1)'	System	21 Sep 2020 16:18:47
	System	21 Sep 2020 16:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:04:44', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '591eb7aa-6661-4490-b656-72cf361df9eb' User entered 'No (N)'	System	21 Sep 2020 16:18:47
	System	21 Sep 2020 16:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:04:50', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '591eb7aa-6661-4490-b656-72cf361df9eb' User entered 'No (N)'	System	21 Sep 2020 16:18:47
	System	21 Sep 2020 16:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:03', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '591eb7aa-6661-4490-b656-72cf361df9eb' User entered 'None (1)'	System	21 Sep 2020 16:18:47
	System	21 Sep 2020 16:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:07', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '591eb7aa-6661-4490-b656-72cf361df9eb' User entered '21 Sep 2020 12:05'	System	21 Sep 2020 16:18:47
	System	21 Sep 2020 16:18:47

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 11:58'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 14:28'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 15:23'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 2'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:48', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '50486bea-8f80-4161-b1dc-e7d9614da6c0' User entered 'None (1)'	System	22 Sep 2020 22:19:01
	System	22 Sep 2020 22:19:01

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:51', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '50486bea-8f80-4161-b1dc-e7d9614da6c0' User entered 'No (N)'	System	22 Sep 2020 22:19:01
	System	22 Sep 2020 22:19:01

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:52', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '50486bea-8f80-4161-b1dc-e7d9614da6c0' User entered 'No (N)'	System	22 Sep 2020 22:19:01
	System	22 Sep 2020 22:19:01

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:54', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '50486bea-8f80-4161-b1dc-e7d9614da6c0' User entered 'None (1)'	System	22 Sep 2020 22:19:01
	System	22 Sep 2020 22:19:01

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:18:58', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '50486bea-8f80-4161-b1dc-e7d9614da6c0' User entered '22 Sep 2020 18:18'	System	22 Sep 2020 22:19:01
	System	22 Sep 2020 22:19:01

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 3'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:38:38', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '38a49ad5-945e-4717-a37e-64d888d4ee57'	System	23 Sep 2020 21:40:13
User entered 'None (1)'	System	23 Sep 2020 21:40:13

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:38:44', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '38a49ad5-945e-4717-a37e-64d888d4ee57' User entered 'No (N)'	System	23 Sep 2020 21:40:13
	System	23 Sep 2020 21:40:13

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:02', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '38a49ad5-945e-4717-a37e-64d888d4ee57' User entered 'No (N)'	System	23 Sep 2020 21:40:13
	System	23 Sep 2020 21:40:13

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:05', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '38a49ad5-945e-4717-a37e-64d888d4ee57'	System	23 Sep 2020 21:40:13
User entered 'None (1)'	System	23 Sep 2020 21:40:13

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:07', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '38a49ad5-945e-4717-a37e-64d888d4ee57' User entered '23 Sep 2020 17:40'	System	23 Sep 2020 21:40:13
	System	23 Sep 2020 21:40:13

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 4'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 5'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 6'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 7'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:26', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '49e8ca93-da2e-4a88-a842-36f4f6c31e2e'	System	27 Sep 2020 16:29:36
User entered 'None (1)'	System	27 Sep 2020 16:29:36

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:27', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '49e8ca93-da2e-4a88-a842-36f4f6c31e2e' User entered 'No (N)'	System	27 Sep 2020 16:29:36
	System	27 Sep 2020 16:29:36

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:29', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '49e8ca93-da2e-4a88-a842-36f4f6c31e2e' User entered 'No (N)'	System	27 Sep 2020 16:29:36
	System	27 Sep 2020 16:29:36

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:30', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '49e8ca93-da2e-4a88-a842-36f4f6c31e2e' User entered 'None (1)'	System	27 Sep 2020 16:29:36
	System	27 Sep 2020 16:29:36

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:29:33', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '49e8ca93-da2e-4a88-a842-36f4f6c31e2e' User entered '27 Sep 2020 12:29'	System	27 Sep 2020 16:29:36
	System	27 Sep 2020 16:29:36

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:18', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered 'None (0)'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:21', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered 'None (0)'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:26', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered 'None (0)'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:35', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered 'None (0)'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:44', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered 'None (0)'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:48', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered 'None (0)'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:05:57', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered 'No (N)'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-21T12:06:01', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '1baca35e-7d5b-44f2-868b-35597a55fa79' User entered '21 Sep 2020 12:06'	System	21 Sep 2020 16:19:14
	System	21 Sep 2020 16:19:14

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 11:58'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 14:28'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Sep 2020 15:23'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 2'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:01', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered 'None (0)'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:02', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered 'None (0)'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:04', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered 'None (0)'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:06', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered 'None (0)'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:07', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered 'None (0)'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:08', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered 'None (0)'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:10', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered 'No (N)'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-22T18:19:14', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd855cca6-00ac-49a5-947d-5d7eb919d3b4' User entered '22 Sep 2020 18:19'	System	22 Sep 2020 22:19:17
	System	22 Sep 2020 22:19:17

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 3'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:14', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50' User entered 'None (0)'	System	23 Sep 2020 21:40:37
	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:18', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50'	System	23 Sep 2020 21:40:37
User entered 'Some interference with activity (2)'	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:20', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50' User entered 'None (0)'	System	23 Sep 2020 21:40:37
	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:23', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50' User entered 'None (0)'	System	23 Sep 2020 21:40:37
	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:26', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50' User entered 'None (0)'	System	23 Sep 2020 21:40:37
	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:28', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50' User entered 'None (0)'	System	23 Sep 2020 21:40:37
	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:31', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50' User entered 'No (N)'	System	23 Sep 2020 21:40:37
	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-23T17:40:34', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '153a3a25-9df9-4359-bced-107a0a8a1a50'	System	23 Sep 2020 21:40:37
User entered '23 Sep 2020 17:40'	System	23 Sep 2020 21:40:37

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 4'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 5'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 6'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	21 Sep 2020 15:46:11
User entered 'Day 7'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:13', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered 'None (0)'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:18', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered 'None (0)'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:20', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered 'None (0)'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:22', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered 'None (0)'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:23', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered 'None (0)'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:25', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered 'None (0)'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:26', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered 'No (N)'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-09-27T12:30:28', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7651eeea-c0f8-43b6-aebb-95327d94a85d' User entered '27 Sep 2020 12:30'	System	27 Sep 2020 16:30:31
	System	27 Sep 2020 16:30:31

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:46:11

US3302455

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:46:11

US3302455

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:52
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	30 Sep 2020 12:14:32

US3302455

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:52
User entered '30 Sep 2020'	Wendy Taylor (b) (4)	30 Sep 2020 12:14:32

US3302455

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:52
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	30 Sep 2020 12:14:32

US3302455

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:52
User entered empty.	Wendy Taylor (b) (4)	30 Sep 2020 12:14:32

US3302455

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:25:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	30 Sep 2020 12:14:36

US3302455

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered '1'	System	30 Sep 2020 12:14:36

US3302455

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:25:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:44:09

US3302455

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:25:28
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:44:09

US3302455

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:25:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 15:44:09

US3302455

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:25:28
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:44:09

US3302455

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:44:12

US3302455

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'I'	System	06 Oct 2020 15:44:12

US3302455

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:34:31

US3302455

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:54
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:34:31

US3302455

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 14:34:31

US3302455

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:55:54
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:34:31

US3302455

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:56:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:34:34

US3302455

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'I'	System	12 Oct 2020 14:34:34

US3302455

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:17
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 14:00:42

US3302455

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:17
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 14:00:42

US3302455

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:17
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	19 Oct 2020 14:00:42

US3302455

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'VISIT2'	System	19 Oct 2020 14:00:42

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '09:15'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '19 Oct 2020 09:15'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '98.2' F	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered empty.	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '66'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'bpm'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '18'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'breaths/min'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '163'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'mmHg'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '90'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'mmHg'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '10:13'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '19 Oct 2020 10:13'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '97.1' F	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered empty.	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '68'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'bpm'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '18'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'breaths/min'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '146'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'mmHg'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:57:43
User entered '81'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'mmHg'	System	19 Oct 2020 15:25:26

US3302455

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:04
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:32

US3302455

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:04
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:32

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:18
User entered empty.	Brittany Belcher (b) (4)	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:18
User entered empty.	Brittany Belcher (b) (4)	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'MRNA-1273 OR PLACEBO'	System	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:18
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:18
User entered '09:43'	Brittany Belcher (b) (4)	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '19 Oct 2020 09:43'	System	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:18
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:18
User entered 'ONCE'	System	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'INTRAMUSCULAR'	System	19 Oct 2020 14:00:36

US3302455

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:29
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:41

US3302455

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:29
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:41

US3302455

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:29
User entered '09:19'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:41

US3302455

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '19 Oct 2020 09:19'	System	19 Oct 2020 15:25:41

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 05:37:57
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Covid result received ' (Site from DM).	Wendy Taylor (b) (4)	23 Dec 2020 03:43:25
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 19-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 11:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:42
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:42
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:42
User entered '09:17'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '19 Oct 2020 09:17'	System	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User closed query 'Please review source and revise if needed. If only one Naso Swab was collected during this visit, then please revise answer to if Naso Swab 2 was collected.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 14:53:03
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:53:01
Query 'Please review source and revise if needed. If only one Naso Swab was collected during this visit, then please revise answer to if Naso Swab 2 was collected.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 13:14:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 13:14:51
User opened query 'Please review source and revise if needed. If only one Naso Swab was collected during this visit, then please revise answer to if Naso Swab 2 was collected.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:50
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:42
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:53:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 13:14:51
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:52
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:59:42
User entered '09:17'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered empty.	System	03 Dec 2020 13:14:51
User entered '19 Oct 2020 09:17'	System	19 Oct 2020 15:25:53

US3302455

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:01:14
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 15:25:56

US3302455

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '1'	System	19 Oct 2020 15:25:56

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:04:21', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd8036208-4878-4b86-9720-0518b63ebbc0' User entered 'Yes (Y)'	System	19 Oct 2020 14:04:39
	System	19 Oct 2020 14:04:39

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:04:27', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd8036208-4878-4b86-9720-0518b63ebbc0' User entered '97.1'	System	19 Oct 2020 14:04:39
	System	19 Oct 2020 14:04:39

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:04:35', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd8036208-4878-4b86-9720-0518b63ebbc0' User entered 'No (N)'	System	19 Oct 2020 14:04:39
	System	19 Oct 2020 14:04:39

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:04:37', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd8036208-4878-4b86-9720-0518b63ebbc0' User entered '19 Oct 2020 10:04'	System	19 Oct 2020 14:04:39
	System	19 Oct 2020 14:04:39

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 10:03'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 12:33'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 13:28'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 2'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:18', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '47f62fd4-bed5-4b03-a3fd-e46a2b5cca72'	System	20 Oct 2020 23:50:32
User entered 'Yes (Y)'	System	20 Oct 2020 23:50:32

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:23', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '47f62fd4-bed5-4b03-a3fd-e46a2b5cca72' User entered '97.9'	System	20 Oct 2020 23:50:32
	System	20 Oct 2020 23:50:32

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:26', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '47f62fd4-bed5-4b03-a3fd-e46a2b5cca72'	System	20 Oct 2020 23:50:32
User entered 'No (N)'	System	20 Oct 2020 23:50:32

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:28', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '47f62fd4-bed5-4b03-a3fd-e46a2b5cca72' User entered '20 Oct 2020 19:50'	System	20 Oct 2020 23:50:32
	System	20 Oct 2020 23:50:32

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 3'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 4'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:21', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8575ca3f-9bda-4fb8-b376-99b36c1c32a9' User entered 'No (N)'	System	23 Oct 2020 15:17:39
	System	23 Oct 2020 15:17:39

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:24', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8575ca3f-9bda-4fb8-b376-99b36c1c32a9'	System	23 Oct 2020 15:17:39
User entered 'No (N)'	System	23 Oct 2020 15:17:39

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:34', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8575ca3f-9bda-4fb8-b376-99b36c1c32a9' User entered '23 Oct 2020 11:17'	System	23 Oct 2020 15:17:39
	System	23 Oct 2020 15:17:39

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 5'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 6'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:25', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '3fbc6a84-228d-407a-a7fc-f35286de52a0' User entered 'Yes (Y)'	System	24 Oct 2020 20:37:40
	System	24 Oct 2020 20:37:40

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:29', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '3fbc6a84-228d-407a-a7fc-f35286de52a0' User entered '97.9'	System	24 Oct 2020 20:37:40
	System	24 Oct 2020 20:37:40

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:36', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '3fbc6a84-228d-407a-a7fc-f35286de52a0' User entered 'No (N)'	System	24 Oct 2020 20:37:40
	System	24 Oct 2020 20:37:40

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:38', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '3fbc6a84-228d-407a-a7fc-f35286de52a0' User entered '24 Oct 2020 16:37'	System	24 Oct 2020 20:37:40
	System	24 Oct 2020 20:37:40

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 7'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:09', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'e42d010d-2fe0-49bc-9f73-9d7a67d27baa' User entered 'Yes (Y)'	System	25 Oct 2020 19:12:24
	System	25 Oct 2020 19:12:24

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:14', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'e42d010d-2fe0-49bc-9f73-9d7a67d27baa' User entered '97.9'	System	25 Oct 2020 19:12:24
	System	25 Oct 2020 19:12:24

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:18', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'e42d010d-2fe0-49bc-9f73-9d7a67d27baa'	System	25 Oct 2020 19:12:24
User entered 'No (N)'	System	25 Oct 2020 19:12:24

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:21', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'e42d010d-2fe0-49bc-9f73-9d7a67d27baa'	System	25 Oct 2020 19:12:24
User entered '25 Oct 2020 15:12'	System	25 Oct 2020 19:12:24

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:04:52', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '261d5a6c-769a-4d29-b849-06bc85d37d10'	System	19 Oct 2020 14:05:10
User entered 'None (1)'	System	19 Oct 2020 14:05:10

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:04:56', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '261d5a6c-769a-4d29-b849-06bc85d37d10'	System	19 Oct 2020 14:05:10
User entered 'No (N)'	System	19 Oct 2020 14:05:10

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:04:58', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '261d5a6c-769a-4d29-b849-06bc85d37d10'	System	19 Oct 2020 14:05:10
User entered 'No (N)'	System	19 Oct 2020 14:05:10

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:02', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '261d5a6c-769a-4d29-b849-06bc85d37d10'	System	19 Oct 2020 14:05:10
User entered 'None (1)'	System	19 Oct 2020 14:05:10

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:06', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '261d5a6c-769a-4d29-b849-06bc85d37d10' User entered '19 Oct 2020 10:05'	System	19 Oct 2020 14:05:10
	System	19 Oct 2020 14:05:10

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 10:03'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 12:33'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 13:28'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 2'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:32', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb6a435d-8302-4c5d-ab84-315ac0b8a82c' User entered 'None (1)'	System	20 Oct 2020 23:50:45
	System	20 Oct 2020 23:50:45

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:35', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb6a435d-8302-4c5d-ab84-315ac0b8a82c' User entered 'No (N)'	System	20 Oct 2020 23:50:45
	System	20 Oct 2020 23:50:45

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:37', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb6a435d-8302-4c5d-ab84-315ac0b8a82c' User entered 'No (N)'	System	20 Oct 2020 23:50:45
	System	20 Oct 2020 23:50:45

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:40', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb6a435d-8302-4c5d-ab84-315ac0b8a82c' User entered 'None (1)'	System	20 Oct 2020 23:50:45
	System	20 Oct 2020 23:50:45

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:43', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'bb6a435d-8302-4c5d-ab84-315ac0b8a82c' User entered '20 Oct 2020 19:50'	System	20 Oct 2020 23:50:45
	System	20 Oct 2020 23:50:45

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 3'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 4'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:38', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7ee9788f-85bf-4e4d-bceb-8cf630178fdb' User entered 'None (1)'	System	23 Oct 2020 15:17:50
	System	23 Oct 2020 15:17:50

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:41', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7ee9788f-85bf-4e4d-bceb-8cf630178fdb' User entered 'No (N)'	System	23 Oct 2020 15:17:50
	System	23 Oct 2020 15:17:50

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:43', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7ee9788f-85bf-4e4d-bceb-8cf630178fdb' User entered 'No (N)'	System	23 Oct 2020 15:17:50
	System	23 Oct 2020 15:17:50

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:44', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7ee9788f-85bf-4e4d-bceb-8cf630178fdb' User entered 'None (1)'	System	23 Oct 2020 15:17:50
	System	23 Oct 2020 15:17:50

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:47', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '7ee9788f-85bf-4e4d-bceb-8cf630178fdb' User entered '23 Oct 2020 11:17'	System	23 Oct 2020 15:17:50
	System	23 Oct 2020 15:17:50

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 5'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 6'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:11', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'dcd1cd73-a02a-4ffe-9c63-f5f043e7a841' User entered 'None (1)'	System	24 Oct 2020 20:37:23
	System	24 Oct 2020 20:37:23

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:14', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'dcd1cd73-a02a-4ffe-9c63-f5f043e7a841' User entered 'No (N)'	System	24 Oct 2020 20:37:23
	System	24 Oct 2020 20:37:23

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:15', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'dcd1cd73-a02a-4ffe-9c63-f5f043e7a841' User entered 'No (N)'	System	24 Oct 2020 20:37:23
	System	24 Oct 2020 20:37:23

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:17', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'dcd1cd73-a02a-4ffe-9c63-f5f043e7a841' User entered 'None (1)'	System	24 Oct 2020 20:37:23
	System	24 Oct 2020 20:37:23

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:20', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'dcd1cd73-a02a-4ffe-9c63-f5f043e7a841' User entered '24 Oct 2020 16:37'	System	24 Oct 2020 20:37:23
	System	24 Oct 2020 20:37:23

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 7'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:24', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '4bcbf32e-71cf-41c8-b528-bef195ca3145'	System	25 Oct 2020 19:12:36
User entered 'None (1)'	System	25 Oct 2020 19:12:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:26', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '4bcbf32e-71cf-41c8-b528-bef195ca3145'	System	25 Oct 2020 19:12:36
User entered 'No (N)'	System	25 Oct 2020 19:12:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:28', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '4bcbf32e-71cf-41c8-b528-bef195ca3145'	System	25 Oct 2020 19:12:36
User entered 'No (N)'	System	25 Oct 2020 19:12:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:29', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '4bcbf32e-71cf-41c8-b528-bef195ca3145'	System	25 Oct 2020 19:12:36
User entered 'None (1)'	System	25 Oct 2020 19:12:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:33', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '4bcbf32e-71cf-41c8-b528-bef195ca3145' User entered '25 Oct 2020 15:12'	System	25 Oct 2020 19:12:36
	System	25 Oct 2020 19:12:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:14', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered 'None (0)'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:16', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered 'None (0)'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:17', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered 'None (0)'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:19', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered 'None (0)'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:20', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered 'None (0)'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:22', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered 'None (0)'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:24', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered 'No (N)'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-19T10:05:30', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '87c555d1-4e6e-43f9-a489-f04fc32bdd7a' User entered '19 Oct 2020 10:05'	System	19 Oct 2020 14:05:38
	System	19 Oct 2020 14:05:38

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 10:03'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 12:33'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '19 Oct 2020 13:28'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 2'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:50:56', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered 'None (0)'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:51:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered 'None (0)'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:51:03', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered 'None (0)'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:51:07', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered 'None (0)'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:51:10', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered 'None (0)'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:51:12', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered 'None (0)'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:51:41', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered 'No (N)'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-20T19:51:44', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '54fe8a56-d28d-40bf-b24e-f965522913ba' User entered '20 Oct 2020 19:51'	System	20 Oct 2020 23:51:45
	System	20 Oct 2020 23:51:45

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 3'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 4'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:51', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered 'None (0)'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:52', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered 'None (0)'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:54', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered 'None (0)'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:55', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered 'None (0)'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:57', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered 'None (0)'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:17:58', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered 'None (0)'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:18:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered 'No (N)'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-23T11:18:03', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '617e96d4-9f2e-4e6f-b89e-ae0649a3b826' User entered '23 Oct 2020 11:18'	System	23 Oct 2020 15:18:06
	System	23 Oct 2020 15:18:06

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 5'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 6'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:42', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00' User entered 'None (0)'	System	24 Oct 2020 20:38:17
	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:47', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00' User entered 'None (0)'	System	24 Oct 2020 20:38:17
	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:53', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00'	System	24 Oct 2020 20:38:17
User entered 'Some interference with activity (2)'	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:37:59', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00'	System	24 Oct 2020 20:38:17
User entered 'No interference with activity (1)'	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:38:02', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00' User entered 'None (0)'	System	24 Oct 2020 20:38:17
	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:38:03', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00' User entered 'None (0)'	System	24 Oct 2020 20:38:17
	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:38:06', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00' User entered 'No (N)'	System	24 Oct 2020 20:38:17
	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-24T16:38:15', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'a3de8e19-d03e-4948-8a05-69f25468cf00' User entered '24 Oct 2020 16:38'	System	24 Oct 2020 20:38:17
	System	24 Oct 2020 20:38:17

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
Data entry locked.	System	19 Oct 2020 14:00:36
User entered 'Day 7'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:42', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered 'None (0)'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:45', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered 'None (0)'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:49', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered 'None (0)'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:53', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered 'None (0)'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:12:57', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered 'None (0)'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:13:02', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered 'None (0)'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:13:06', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered 'No (N)'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2020-10-25T15:13:11', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '44c40175-bc68-405d-b3ad-6d353f1e06b9' User entered '25 Oct 2020 15:13'	System	25 Oct 2020 19:13:15
	System	25 Oct 2020 19:13:15

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 14:00:36

US3302455

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:57:58
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 14:00:36

US3302455

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:17:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 16:46:59

US3302455

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:17:10
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 16:46:59

US3302455

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:17:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 16:46:59

US3302455

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:17:10
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 16:46:59

US3302455

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:17:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 16:47:02

US3302455

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'I'	System	27 Oct 2020 16:47:02

US3302455

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:21:45
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	02 Nov 2020 19:40:37

US3302455

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:21:45
User entered '2 Nov 2020'	Brittany Belcher (b) (4)	02 Nov 2020 19:40:37

US3302455

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:21:45
User entered 'Contact Made (CONTACT MADE)'	Brittany Belcher (b) (4)	02 Nov 2020 19:40:37

US3302455

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:21:45
User entered empty.	Brittany Belcher (b) (4)	02 Nov 2020 19:40:37

US3302455

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:21:52
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	02 Nov 2020 19:40:41

US3302455

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'I'	System	02 Nov 2020 19:40:41

US3302455

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:22:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 14:08:51

US3302455

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:22:21
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 14:08:51

US3302455

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:22:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 14:08:51

US3302455

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:22:21
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 14:08:51

US3302455

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:22:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 14:08:43

US3302455

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'I'	System	09 Nov 2020 14:08:43

US3302455

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:23:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:14:48

US3302455

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:23:54
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 19:14:48

US3302455

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:23:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Nov 2020 19:14:48

US3302455

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'VISIT3'	System	16 Nov 2020 19:14:48

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered '09:24'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '16 Nov 2020 09:24'	System	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered '98.3' F	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered '64'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'bpm'	System	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered '18'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'breaths/min'	System	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered '152'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'mmHg'	System	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:15
User entered '79'	(b) (4), (b) (6)	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'mmHg'	System	16 Nov 2020 19:15:17

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14

US3302455

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14

US3302455

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:15:22

US3302455

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:24:26
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 19:15:22

US3302455

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:30:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:15:31

US3302455

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:30:30
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 19:15:31

US3302455

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:30:30
User entered '09:48'	(b) (4), (b) (6)	16 Nov 2020 19:15:31

US3302455

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered '16 Nov 2020 09:48'	System	16 Nov 2020 19:15:31

US3302455

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:30:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:15:34

US3302455

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:14
User entered 'I'	System	16 Nov 2020 19:15:34

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-13T14:56:41', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9a332aea-a162-45f8-bb83-90e715ebf144' User entered 'No (N)'	System	13 Jan 2021 19:56:52
	System	13 Jan 2021 19:56:52

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-13T14:56:45', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9a332aea-a162-45f8-bb83-90e715ebf144' User entered 'No (N)'	System	13 Jan 2021 19:56:52

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-13T14:56:47', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9a332aea-a162-45f8-bb83-90e715ebf144' User entered '13 Jan 2021 14:56:47'	System	13 Jan 2021 19:56:52
	System	13 Jan 2021 19:56:52

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-20T06:27:40', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'b920a0e0-be7f-4580-9205-f55c71c9926a' User entered 'No (N)'	System	20 Jan 2021 11:28:01

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-20T06:27:42', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'b920a0e0-be7f-4580-9205-f55c71c9926a' User entered 'No (N)'	System	20 Jan 2021 11:28:01

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-20T06:27:57', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'b920a0e0-be7f-4580-9205-f55c71c9926a' User entered '20 Jan 2021 06:27:57'	System	20 Jan 2021 11:28:01
	System	20 Jan 2021 11:28:01

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-27T15:16:55', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd78c85ba-5c96-4bf2-9066-d2dc981363d2' User entered 'No (N)'	System	27 Jan 2021 20:17:02
	System	27 Jan 2021 20:17:02

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-27T15:16:57', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd78c85ba-5c96-4bf2-9066-d2dc981363d2' User entered 'No (N)'	System	27 Jan 2021 20:17:02

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-01-27T15:17:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'd78c85ba-5c96-4bf2-9066-d2dc981363d2' User entered '27 Jan 2021 15:17:00'	System	27 Jan 2021 20:17:02
	System	27 Jan 2021 20:17:02

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-03T11:58:55', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '07486fac-f07d-46a3-a31b-acd3d1f6d90e' User entered 'No (N)'	System	03 Feb 2021 16:59:08
	System	03 Feb 2021 16:59:08

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-03T11:59:01', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '07486fac-f07d-46a3-a31b-acd3d1f6d90e' User entered 'No (N)'	System	03 Feb 2021 16:59:08
	System	03 Feb 2021 16:59:08

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-03T11:59:04', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '07486fac-f07d-46a3-a31b-acd3d1f6d90e' User entered '03 Feb 2021 11:59:04'	System	03 Feb 2021 16:59:08
	System	03 Feb 2021 16:59:08

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-10T07:08:20', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '80f83618-5519-49c1-a7ac-ad2103d2c71b' User entered 'No (N)'	System	10 Feb 2021 12:08:29
	System	10 Feb 2021 12:08:29

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-10T07:08:23', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '80f83618-5519-49c1-a7ac-ad2103d2c71b' User entered 'No (N)'	System	10 Feb 2021 12:08:29
	System	10 Feb 2021 12:08:29

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-10T07:08:26', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '80f83618-5519-49c1-a7ac-ad2103d2c71b' User entered '10 Feb 2021 07:08:26'	System	10 Feb 2021 12:08:29
	System	10 Feb 2021 12:08:29

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-17T23:44:53', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'f9b53d6e-b512-4147-a469-33b9556cd3bf' User entered 'No (N)'	System	18 Feb 2021 04:45:05
	System	18 Feb 2021 04:45:05

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-17T23:44:55', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'f9b53d6e-b512-4147-a469-33b9556cd3bf' User entered 'No (N)'	System	18 Feb 2021 04:45:05
	System	18 Feb 2021 04:45:05

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-17T23:44:59', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'f9b53d6e-b512-4147-a469-33b9556cd3bf' User entered '17 Feb 2021 23:44:59'	System	18 Feb 2021 04:45:05

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-24T12:43:10-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'aebae3e5-4a1e-4118-88bc-8adfb7318a9f' User entered 'No (N)'	System	24 Feb 2021 17:43:17

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-24T12:43:11-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'aebae3e5-4a1e-4118-88bc-8adfb7318a9f' User entered 'No (N)'	System	24 Feb 2021 17:43:17

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-02-24T12:43:14-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'aebae3e5-4a1e-4118-88bc-8adfb7318a9f' User entered '24 Feb 2021 17:43:14'	System	24 Feb 2021 17:43:17
	System	24 Feb 2021 17:43:17

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-04T18:00:39-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'be4d4415-a242-4293-a5f9-b7a58bd96793'	System	04 Mar 2021 23:03:24
User entered 'No (N)'	System	04 Mar 2021 23:03:24

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-04T18:00:41-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'be4d4415-a242-4293-a5f9-b7a58bd96793'	System	04 Mar 2021 23:03:24
User entered 'No (N)'	System	04 Mar 2021 23:03:24

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-04T18:00:58-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'be4d4415-a242-4293-a5f9-b7a58bd96793'	System	04 Mar 2021 23:03:24
User entered '04 Mar 2021 23:00:58'	System	04 Mar 2021 23:03:24

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-11T12:31:10-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9c5ebedf-627d-449a-8e17-4964f9f36d3e' User entered 'Yes (Y)'	System	11 Mar 2021 17:31:55
	System	11 Mar 2021 17:31:55

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-11T12:31:16-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9c5ebedf-627d-449a-8e17-4964f9f36d3e'	System	11 Mar 2021 17:31:55
User entered 'No (N)'	System	11 Mar 2021 17:31:55

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-11T12:31:25-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9c5ebedf-627d-449a-8e17-4964f9f36d3e'	System	11 Mar 2021 17:31:55
User entered 'No (N)'	System	11 Mar 2021 17:31:55

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-11T12:31:35-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9c5ebedf-627d-449a-8e17-4964f9f36d3e' User entered 'Yes (Y)'	System	11 Mar 2021 17:31:55
	System	11 Mar 2021 17:31:55

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-11T12:31:40-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9c5ebedf-627d-449a-8e17-4964f9f36d3e'	System	11 Mar 2021 17:31:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Mar 2021 17:31:55

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-11T12:31:44-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9c5ebedf-627d-449a-8e17-4964f9f36d3e' User entered '11 Mar 2021 17:31:44'	System	11 Mar 2021 17:31:55
	System	11 Mar 2021 17:31:55

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-18T20:28:44-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '73ab12a9-f2d6-48a9-9a6f-b48071fca991'	System	19 Mar 2021 00:28:53
User entered 'No (N)'	System	19 Mar 2021 00:28:53

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-18T20:28:46-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '73ab12a9-f2d6-48a9-9a6f-b48071fca991'	System	19 Mar 2021 00:28:53
User entered 'No (N)'	System	19 Mar 2021 00:28:53

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-18T20:28:49-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '73ab12a9-f2d6-48a9-9a6f-b48071fca991'	System	19 Mar 2021 00:28:53
User entered '18 Mar 2021 20:28:49'	System	19 Mar 2021 00:28:53

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-24T21:16:26-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '48f6fcc1-7458-418e-94cb-7800d80e3917'	System	25 Mar 2021 01:24:31
User entered 'No (N)'	System	25 Mar 2021 01:24:31

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-24T21:16:28-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '48f6fcc1-7458-418e-94cb-7800d80e3917'	System	25 Mar 2021 01:24:31
User entered 'No (N)'	System	25 Mar 2021 01:24:31

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-24T21:16:31-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '48f6fcc1-7458-418e-94cb-7800d80e3917'	System	25 Mar 2021 01:24:31
User entered '24 Mar 2021 21:16:31'	System	25 Mar 2021 01:24:31

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-02T07:44:44-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8723d590-a10f-407e-95ed-03106c091818' User entered 'No (N)'	System	02 Apr 2021 11:44:57
	System	02 Apr 2021 11:44:57

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-02T07:44:47-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8723d590-a10f-407e-95ed-03106c091818' User entered 'No (N)'	System	02 Apr 2021 11:44:57
	System	02 Apr 2021 11:44:57

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-02T07:44:53-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8723d590-a10f-407e-95ed-03106c091818'	System	02 Apr 2021 11:44:57
User entered '02 Apr 2021 07:44:53'	System	02 Apr 2021 11:44:57

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-07T18:49:50-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8bbd9ae7-c61b-4ae4-9c81-f20d28c1b001'	System	07 Apr 2021 22:50:00
User entered 'No (N)'	System	07 Apr 2021 22:50:00

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-07T18:49:52-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8bbd9ae7-c61b-4ae4-9c81-f20d28c1b001'	System	07 Apr 2021 22:50:00
User entered 'No (N)'	System	07 Apr 2021 22:50:00

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-07T18:49:55-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '8bbd9ae7-c61b-4ae4-9c81-f20d28c1b001'	System	07 Apr 2021 22:50:00
User entered '07 Apr 2021 18:49:55'	System	07 Apr 2021 22:50:00

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-14T16:33:30-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9e8e4039-e174-44df-8a90-f05eb514b8ff' User entered 'No (N)'	System	14 Apr 2021 20:33:40
	System	14 Apr 2021 20:33:40

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-14T16:33:34-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9e8e4039-e174-44df-8a90-f05eb514b8ff' User entered 'No (N)'	System	14 Apr 2021 20:33:40
	System	14 Apr 2021 20:33:40

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-14T16:33:37-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: '9e8e4039-e174-44df-8a90-f05eb514b8ff' User entered '14 Apr 2021 16:33:37'	System	14 Apr 2021 20:33:40
	System	14 Apr 2021 20:33:40

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-21T15:00:02-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'c6238b87-1df8-41ad-ba96-2f6b2cb5ba31' User entered 'No (N)'	System	21 Apr 2021 19:00:13
	System	21 Apr 2021 19:00:13

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-21T15:00:04-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'c6238b87-1df8-41ad-ba96-2f6b2cb5ba31' User entered 'No (N)'	System	21 Apr 2021 19:00:13
	System	21 Apr 2021 19:00:13

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-21T15:00:06-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'c6238b87-1df8-41ad-ba96-2f6b2cb5ba31'	System	21 Apr 2021 19:00:13
User entered '21 Apr 2021 15:00:06'	System	21 Apr 2021 19:00:13

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-28T20:02:28-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'acb9acc0-92c9-41ba-bb19-e6f23b32d004' User entered 'No (N)'	System	29 Apr 2021 00:02:38

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

Have you been exposed to someone with 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 (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-28T20:02:31-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'acb9acc0-92c9-41ba-bb19-e6f23b32d004'	System	29 Apr 2021 00:02:38
User entered 'No (N)'	System	29 Apr 2021 00:02:38

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-04-28T20:02:33-04:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'acb9acc0-92c9-41ba-bb19-e6f23b32d004' User entered '28 Apr 2021 20:02:33'	System	29 Apr 2021 00:02:38
	System	29 Apr 2021 00:02:38

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 09:53:44

US3302455

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:53:44
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 09:53:44

US3302455

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:02:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-04T18:01:17-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'fb777bd2-0c40-43f0-a924-8f8a4c93ba10'	System	04 Mar 2021 23:04:29
User entered 'No (N)'	System	04 Mar 2021 23:04:29

US3302455

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:02:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F8B4435-7ED4-4A8A-BB44-A064EEA012C1)', Time: '2021-03-04T18:01:21-05:00', User OID: 'PatientReportedOutcome (US3302455)', ODM File OID: 'fb777bd2-0c40-43f0-a924-8f8a4c93ba10'	System	04 Mar 2021 23:04:29
User entered '04 Mar 2021 23:01:21'	System	04 Mar 2021 23:04:29

US3302455

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:05:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 13:13:36

US3302455

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:05:08
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 13:13:36

US3302455

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:05:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 13:13:36

US3302455

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:05:08
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 13:13:36

US3302455

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:05:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 13:13:41

US3302455

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:25:10
User entered 'I'	System	17 Dec 2020 13:13:41

US3302455

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:08:02
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	18 Jan 2021 16:24:39

US3302455

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:08:02
User entered '18 Jan 2021'	Kendal Nelson (b) (4)	18 Jan 2021 16:24:39

US3302455

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:08:02
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4)	18 Jan 2021 16:24:39

US3302455

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:08:02
User entered empty.	Kendal Nelson (b) (4)	18 Jan 2021 16:24:39

US3302455

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:08:07
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	18 Jan 2021 16:24:42

US3302455

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User entered '1'	System	18 Jan 2021 16:24:42

US3302455

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 01:28:44
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	15 Feb 2021 18:18:28

US3302455

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 01:28:44
User entered '15 Feb 2021'	Kendal Nelson (b) (4)	15 Feb 2021 18:18:28

US3302455

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 01:28:44
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4)	15 Feb 2021 18:18:28

US3302455

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 01:28:44
User entered empty.	Kendal Nelson (b) (4)	15 Feb 2021 18:18:28

US3302455

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 01:28:51
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	15 Feb 2021 18:18:32

US3302455

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:32
User entered '1'	System	15 Feb 2021 18:18:32

US3302455

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:20:17
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:46:20
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	15 Mar 2021 20:13:18

US3302455

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:20:17
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:46:20
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '15 Mar 2021'	Kendal Nelson (b) (4)	15 Mar 2021 20:13:18

US3302455

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:20:17
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:46:20
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4)	15 Mar 2021 20:13:18

US3302455

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:20:17
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:46:20
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered empty.	Kendal Nelson (b) (4)	15 Mar 2021 20:13:18

US3302455

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:20:17
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:46:41
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	15 Mar 2021 20:13:22

US3302455

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:20:17
User entered 'I'	System	15 Mar 2021 20:13:22

US3302455

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:05:21

US3302455

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:05:21

US3302455

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Apr 2021 17:05:21

US3302455

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 17:05:21

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '09:53'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 09:53'	System	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '97.7' F	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '154'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '81'	(b) (4), (b) (6)	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 17:05:50

US3302455

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:06:07

US3302455

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:06:07

US3302455

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:06:19

US3302455

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:06:19

US3302455

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered '09:57'	(b) (4), (b) (6)	20 Apr 2021 17:06:19

US3302455

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 09:57'	System	20 Apr 2021 17:06:19

US3302455

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:06:46

US3302455

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:06:46

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:49:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 13:17:49

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:49:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:17:49

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[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 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:49:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:17:49

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 13:17:49

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:50:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:48:42
User entered '0'	Brittany Belcher (b) (4)	12 Apr 2021 17:51:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:12:51

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:50:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:48:40
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:39:40
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated. ' (Site from DM).	Brittany Belcher (b) (4)	12 Apr 2021 17:52:06
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brittany Belcher (b) (4)	12 Apr 2021 17:51:50
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:17:40
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:12:51

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:50:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:50:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:50:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:39:46
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:50:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:39:46
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:50:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '1'	System	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:02:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '1'	System	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered empty.	System	15 Jan 2021 13:19:17
DataPoint set to visible.	System	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered empty.	System	15 Jan 2021 13:19:17
DataPoint set to visible.	System	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '09:41'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '14 Jan 2021 09:41'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '74'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'bpm'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'breaths/min'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '157'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'mmHg'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '77'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'mmHg'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered empty.	System	15 Jan 2021 13:19:17
DataPoint set to visible.	System	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '10:28'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '14 Jan 2021 10:28'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '67'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'bpm'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'breaths/min'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '154'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'mmHg'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:53:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '75'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'mmHg'	System	15 Jan 2021 13:19:17

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:09
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:25

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:09
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:25

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'mRNA-1273'	System	15 Jan 2021 13:19:36
DataPoint set to visible.	System	15 Jan 2021 13:18:30

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '09:52'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '14 Jan 2021 09:52'	System	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:54:38
User entered 'ONCE'	System	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 13:19:36

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:51:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:03

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:51:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:03

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:51:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '09:25'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:03

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '14 Jan 2021 09:25'	System	15 Jan 2021 13:18:03

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:52:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:11

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:52:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:11

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:52:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '09:23'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:18:11

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:30

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '14 Jan 2021 09:23'	System	15 Jan 2021 13:18:11

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:52:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:19:57

US3302455

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:11:59
User entered '1'	System	15 Jan 2021 13:19:57

US3302455

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:47:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:55:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	22 Jan 2021 20:14:06

US3302455

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:47:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:55:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered '22 Jan 2021'	Wendy Taylor (b) (4)	22 Jan 2021 20:14:06

US3302455

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:47:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:55:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	22 Jan 2021 20:14:06

US3302455

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:47:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:55:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered empty.	(b) (4)	22 Jan 2021 20:14:06

US3302455

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:47:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:55:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	22 Jan 2021 20:14:12

US3302455

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:47:29
User entered 'I'	System	22 Jan 2021 20:14:12

US3302455

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:47:29
User entered 'I'	System	22 Jan 2021 20:14:12
DataPoint set to visible.	System	22 Jan 2021 20:14:12

US3302455

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:56:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:51:49

US3302455

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 11FEB2021 is reported under OL-2 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 20:28:22
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 11FEB2021 is reported under OL-2 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Unscheduled visit added. ' (Site from DM).	Brittany Belcher (b) (4)	12 Apr 2021 20:38:59
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 11FEB2021 is reported under OL-2 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:27:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:56:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:51:49

US3302455

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:56:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:51:49

US3302455

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'OLD29'	System	11 Feb 2021 18:51:49

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '10:44'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered '11 Feb 2021 10:44'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '85'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'bpm'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '16'	(b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'breaths/min'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '142'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'mmHg'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '82'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'mmHg'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '11:20'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered '11 Feb 2021 11:20'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '97.8' F	(b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '70'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'bpm'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'breaths/min'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '99'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'mmHg'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:57:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '60'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'mmHg'	System	11 Feb 2021 18:52:42

US3302455

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:32
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:49:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 14:49:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:48

US3302455

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:32
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:08:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:49:45
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 14:49:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:48

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'mRNA-1273'	System	11 Feb 2021 18:52:59
DataPoint set to visible.	System	22 Jan 2021 20:14:12

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered '10:50'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered '11 Feb 2021 10:50'	System	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:59:49
User entered 'ONCE'	System	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 18:52:59

US3302455

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:00:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:53:26

US3302455

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:13:27
User entered 'I'	System	11 Feb 2021 18:53:26

US3302455

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:00:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	18 Feb 2021 13:29:46

US3302455

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:00:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered '18 Feb 2021'	(b) (4) Wendy Taylor (b) (4)	18 Feb 2021 13:29:46

US3302455

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:00:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	18 Feb 2021 13:29:46

US3302455

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:00:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered empty.	Wendy Taylor (b) (4)	18 Feb 2021 13:29:46

US3302455

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:01:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:30:19
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	18 Feb 2021 13:30:23

US3302455

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:19
User entered 'I'	System	18 Feb 2021 13:30:23

US3302455

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:11

US3302455

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:11

US3302455

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[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 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:11

US3302455

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
User entered 'OLD57'	System	11 Mar 2021 21:06:11

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '08:48'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
User entered '11 Mar 2021 08:48'	System	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '89'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
User entered 'bpm'	System	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
User entered 'breaths/min'	System	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '153'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
User entered 'mmHg'	System	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '86'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
User entered 'mmHg'	System	11 Mar 2021 21:06:30

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02

US3302455

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02

US3302455

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:03:12
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:34

US3302455

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:03:12
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:34

US3302455

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:03:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:42

US3302455

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:03:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:42

US3302455

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:03:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '08:50'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:06:42

US3302455

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:02
User entered '11 Mar 2021 08:50'	System	11 Mar 2021 21:06:42

US3302455

Folder: **Unscheduled 11 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:30**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:17
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:36
User entered '11 Feb 2021'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:37

US3302455

Folder: **Unscheduled 11 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:30**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:17
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:36
User entered '0'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:37

US3302455

Folder: Unscheduled 11 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:30

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:17
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:36
User entered '0'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:37

US3302455

Folder: **Unscheduled 11 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:30**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:17
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:36
User entered 'l'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:37

US3302455

Folder: **Unscheduled 11 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:30**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:17
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:36
User entered '0'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:37

US3302455

Folder: Unscheduled 11 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:21
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:45
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:49

US3302455

Folder: Unscheduled 11 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:21
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:45
User entered '11 Feb 2021'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:49

US3302455

Folder: Unscheduled 11 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:21
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:50:45
User entered '10:46'	Brittany Belcher (b) (4)	12 Apr 2021 20:38:49

US3302455

Folder: **Unscheduled 11 Feb 2021**

Form: **Immunogenicity Assessment**

Generated On: **09 Jun 2021 17:02:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:21
User entered '11 Feb 2021 10:46'	System	12 Apr 2021 20:38:49

US3302455

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:02:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:04
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
DataPoint Un-verified.	(b) (4)	
	Brittany Belcher (b) (4)	11 Mar 2021 14:55:33
Signature has been broken.	Brittany Belcher (b) (4)	11 Mar 2021 14:55:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	11 Mar 2021 14:55:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:28:44
User entered 'No (N)'	brittany cooksey (b) (4)	23 Nov 2020 02:22:05
	(b) (4)	

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:56:28
User entered		
'USA-US087-2021-mRNA-1273-P301000023'	System	12 Mar 2021 14:56:14
User entered 'New'	(b) (4), (b) (6)	12 Mar 2021 14:56:14

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:08
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 19:46:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 19:46:58
Data point term sent to Coder	System	11 Mar 2021 15:16:28
User entered 'Acute CVA'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:10
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:12
User entered 'No (N)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:14
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.	(b) (4), (b) (6)	18 Mar 2021 01:23:55
' canceled (Site from Safety).		
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	17 Mar 2021 19:46:16
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.	(b) (4), (b) (6)	12 Mar 2021 15:02:22
' (Site from Safety).		
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:17
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:19
User entered empty.	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:21
User entered 'No (N)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Mar 2021 15:16:39
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	11 Mar 2021 15:16:39
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Mar 2021 15:15:54
User entered '10 Mar 2021'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:34
User entered empty.	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:40
User entered 'Grade 4 (Grade 4)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:44
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:05:58
User entered '0'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:01
User entered 'I'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:05
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 17:14:22
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Sent for medical records. Will update as soon as records are received. ' (Site from Safety).	Brittany Belcher (b) (4)	26 Mar 2021 13:29:15
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:44:57
User entered 'I'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:09
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:12
User entered '10 Mar 2021'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:15
User entered 'No (N)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:25
User entered empty.	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:27
User entered '0'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:28
User entered '0'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:32
User entered '0'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:35
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:36
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

US3302455

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:38
User entered 'Not Applicable (NOT APPLICABLE)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

None

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:06:40
User entered '0'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
User closed query 'Per CDM CLR re-query: Thank you for your answer. However, please keep this query open until there is information what to enter. Thank you!' (Site from DM).	(b) (4)	
Query 'Per CDM CLR re-query: Thank you for your answer. However, please keep this query open until there is information what to enter. Thank you!' answered with 'Con Med and Medical History list have been updated. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 10:57:46
DataPoint Verified.		
User opened query 'Per CDM CLR re-query: Thank you for your answer. However, please keep this query open until there is information what to enter. Thank you!' (Site from DM).	Brittany Belcher (b) (4)	22 Apr 2021 20:13:35
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. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Sent for medical records. Will update as soon as records are received. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 21:06:58
	(b) (4), (b) (6)	29 Mar 2021 06:52:12
	(b) (4), (b) (6)	29 Mar 2021 06:52:12
	Brittany Belcher (b) (4)	26 Mar 2021 13:29:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[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. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered 'I'	(b) (4), (b) (6) [REDACTED] Brittany Belcher (b) (4) [REDACTED] [REDACTED]	23 Mar 2021 03:34:42 11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:07:00
User entered '0'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
User closed query 'Please review source and revise if needed. Source states that outcome of AE is Recovering/Resolving.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 16:55:53
Query 'Please review source and revise if needed. Source states that outcome of AE is Recovering/Resolving.' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	22 Apr 2021 20:13:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:57:54
User opened query 'Please review source and revise if needed. Source states that outcome of AE is Recovering/Resolving.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 21:07:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Brittany Belcher (b) (4)	11 Mar 2021 15:16:39
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:07:43
User entered empty.	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
User closed query 'Please confirm subject's use of insulin glargine, amlodipine, benztropine, clobetasol propionate, clopidogrel, losartan, memantine, olanzapine, oxygen, and paroxetine met criteria as concomitant medications (received within 30 days prior to event). If so, please provide these as concomitant medication along with start dates and indications?' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:42:34
Query 'Please confirm subject's use of insulin glargine, amlodipine, benztropine, clobetasol propionate, clopidogrel, losartan, memantine, olanzapine, oxygen, and paroxetine met criteria as concomitant medications (received within 30 days prior to event). If so, please provide these as concomitant medication along with start dates and indications?' answered with 'All listed Con Meds are listed in the Con Med list with indications. Insulin gargline (Con Med 11, Amlodipine Con Med 12, benztropine Con Med 13, clobetasol propianate Con Med 14, Clopidogrel con Med 15, losartan con med 17, memantine con med 18, olanzapine con med 19, oxygen con med 20, paroxetine con med 21. Confirmed with patient that some meds were not reported at the beginning of study and were added as soon as site received/reviewed records along with confirming with patient. ' (Site from Safety).	Brittany Belcher (b) (4)	29 Apr 2021 13:29:23
User opened query 'Please confirm subject's use of insulin glargine, amlodipine, benztropine, clobetasol propionate, clopidogrel, losartan, memantine, olanzapine, oxygen, and paroxetine met criteria as concomitant medications (received within 30 days prior to event). If so, please provide these as concomitant medication along with start dates and indications?' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 19:58:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:56:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Narrative](#)

Audit	User	Time (GMT)
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:59:35
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)	23 Apr 2021 12:59:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:59:25
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)	23 Apr 2021 12:59:21
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Redacted medical records sent. ' (Site from Safety).	Brittany Belcher (b) (4)	22 Apr 2021 20:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[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 'Redacted medical records sent. ' (Site from Safety).	Brittany Belcher (b) (4)	22 Apr 2021 20:46:34
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Redacted medical records sent. ' (Site from Safety).	Brittany Belcher (b) (4)	22 Apr 2021 20:46:28
DataPoint Un-verified.	Brittany Belcher (b) (4)	22 Apr 2021 20:45:58
User entered 'SUBJECT PRESENTED TO SITE AND COMPLETED OL V3 AND REPORTED HAVING BEEN HOSPITALIZED FOR AN ACUTE CVA. MEDICAL RECORD RELEASE FORM COMPLETED AND SENT VIA FAX. ONCE RECORDS ARE RECEIVED/REVIEWED, CON MEDS LIST WILL BE UPDATED. 4/22/2021: Medical Records regarding SAE has been received/reviewed. All Con Meds, medical history, and AE's lists updated in source and EDC. IRB was updated.' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 20:45:58
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Subject was not hospitalized due to COVID-19. therefore no testing relating to Covid-19 was completed. ' (Site from Safety).	Brittany Belcher (b) (4)	22 Apr 2021 20:15:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Narrative](#)

Audit	User	Time (GMT)
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:19:42
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)	29 Mar 2021 18:19:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:19:32
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)	29 Mar 2021 18:19:27
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)	29 Mar 2021 17:14:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 17:14:29
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)	29 Mar 2021 17:14:27
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 'Sent for medical records. Will update as soon as records are received. ' (Site from Safety).	Brittany Belcher (b) (4)	26 Mar 2021 13:30:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Sent for medical records. Will update as soon as records are received. ' (Site from Safety).	Brittany Belcher (b) (4)	26 Mar 2021 13:29:51
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 'Sent for medical records. Will update as soon as records are received. ' (Site from Safety).	Brittany Belcher (b) (4)	26 Mar 2021 13:29:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[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 Mar 2021 14:43:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:43:13
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)	16 Mar 2021 14:43:02
User entered 'Subject presented to site and completed OL V3 and reported having been hospitalized for an Acute CVA. Medical record release form completed and sent via fax. Once records are received/reviewed, Con Meds list will be updated.'	Brittany Belcher (b) (4)	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 15:15:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 15:15:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:02:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:33
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 14:08:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:47
Data point term sent to Coder	System	29 Oct 2020 14:09:37
User entered 'pantoprazole'	Brittany Belcher (b) (4) 	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'gerd'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '40'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'mg (mg)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'un Jun 2020'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '0'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:11

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:09:11

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:09:11

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:09:11

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: INDAPAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:42:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:42:43
Data point term sent to Coder	System	29 Oct 2020 16:11:39
Data point term sent to Coder	System	29 Oct 2020 14:09:47
User entered 'indapamide'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Hypertension' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 16:11:27
User entered 'HTN'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '1.25'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'mg (mg)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'un May 2020'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '0'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:09:41

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:48:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:48:54
Data point term sent to Coder	System	08 Dec 2020 15:47:35
Coding entries removed.	brittany cooksey (b) (4)	08 Dec 2020 15:47:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:51:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:51:56
Data point term sent to Coder	System	29 Oct 2020 14:10:47
User entered 'victoza'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'diabetes type 2'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:09:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:27:24
DataPoint Un-verified.	brittany cooksey (b) (4)	08 Dec 2020 15:47:36
	(b) (4)	
	brittany cooksey (b) (4)	08 Dec 2020 15:47:23
	(b) (4)	
User entered '1.2' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 15:47:23
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 14:25:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '5'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'mg (mg)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:09:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:27:26
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 15:48:27
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 15:47:23
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 15:47:23
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 14:25:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'un May 2020'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '0'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Yes (Y)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:10:08

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:51:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:51:57
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 14:10:48
User entered 'glipizide'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'diabetes type 2'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '5'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'mg (mg)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'un May 2020'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '0'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Yes (Y)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:10:32

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:43:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:43:59
Data point term sent to Coder	System	29 Oct 2020 16:11:40
Data point term sent to Coder	System	29 Oct 2020 14:11:51
User entered 'lisinopril'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Hypertension' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 16:11:40
User entered 'HTN'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '10'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'mg (mg)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4) 	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '0'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:10:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 03:52:03
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	30 Oct 2020 03:52:03
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	29 Oct 2020 14:11:51
User entered 'simvastatin'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'hypercholesterolemia'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '40'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'mg (mg)'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered '0'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:18:02
DataPoint Un-verified.	Brittany Belcher (b) (4)	22 Apr 2021 19:50:30
Signature has been broken.	Brittany Belcher (b) (4)	22 Apr 2021 19:50:30
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 19:50:30
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:18:11
DataPoint Un-verified.	Brittany Belcher (b) (4)	22 Apr 2021 19:50:30
Signature has been broken.	Brittany Belcher (b) (4)	22 Apr 2021 19:50:30
User entered '06 Mar 2021' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 19:50:30
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:28:36
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User entered '1'	System	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User entered '1'	System	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:51
User entered '804 (804)'	System	29 Oct 2020 14:11:36

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 19:55:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 19:55:10
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 19:54:35
User entered 'Clonidine'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0.1'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '11 Feb 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '11 Feb 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User entered '1'	System	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User entered '1'	System	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User entered '804 (804)'	System	22 Apr 2021 19:53:49

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
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)	22 Apr 2021 19:55:09
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	System	22 Apr 2021 19:54:33
User entered 'Aspirin'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'DVT Prophylaxis'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '325'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 19:54:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
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)	22 Apr 2021 19:56:11
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	22 Apr 2021 19:56:11
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	22 Apr 2021 19:55:36
User entered 'Atovastatin'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypercholesterolemia'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '80'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 19:55:07

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SODIUM, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 19:56:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 19:56:59
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 19:56:37
User entered 'Sodium Chloride'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hyponatremia'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '1'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'g (g)'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '16 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User entered '2'	System	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User entered '1'	System	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:18
User entered '804 (804)'	System	22 Apr 2021 19:56:05

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 19:58:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 19:58:15
Data point term sent to Coder	System	22 Apr 2021 19:57:38
User entered 'Lantus'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Diabetes Type II'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '35'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'IU (IU)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'q 12 hours'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:57:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 19:59:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 19:59:03
Data point term sent to Coder	System	22 Apr 2021 19:58:43
User entered 'Amlodipine'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 19:57:44

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: ANTICHOLINERGIC AGENTS, ATC: ETHERS OF TROPINE OR TROPINE DERIVATIVES, PRODUCT: BENZATROPINE MESILATE, PRODUCTSYNONYM: COGENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 19:59:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 19:59:03
Data point term sent to Coder	System	22 Apr 2021 19:58:42
User entered 'Cogentin'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Anxiety'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'I'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 19:58:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE, PRODUCTSYNONYM: CLOBETASOL 0.05% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:57:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:57:42
Data point term sent to Coder	System	22 Apr 2021 19:59:43
User entered 'Clobestasol (0.05%)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Onychomycosis'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'I'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'application'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Topical (TOPICAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '11 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 19:59:16

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
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.	Coder Import (b) (4)	23 Apr 2021 02:04:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:04:45
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:00:44
User entered 'Clopidogrel'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 20:12:42
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'DVT Prophylaxis'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '75'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '07 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 19:59:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: INDAPAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:02:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:02:09
Data point term sent to Coder	System	22 Apr 2021 20:00:47
User entered 'Inadapamide'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '1.25'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '11 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 20:00:21

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
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.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:02:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:02:09
Data point term sent to Coder	System	22 Apr 2021 20:01:49
User entered 'Losartan'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '25'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '11 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 20:00:52

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: OTHER ANTI-DEMENTIA DRUGS, PRODUCT: MEMANTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:16:41
Data point term sent to Coder	System	22 Apr 2021 20:03:01
User entered 'Memantine'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Alzheimer's Disease'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 20:02:02

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:40:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:40:41
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:03:01
User entered 'Olanzapine'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Bi-Polar Disease'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '20'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 20:02:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 20:02:49
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 20:02:49
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 20:02:30
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	22 Apr 2021 20:02:49
User entered '06 Mar 2021' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 20:02:49
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	22 Apr 2021 20:02:30
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 20:02:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 20:02:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 20:02:49
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 20:02:30
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 20:02:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 20:02:49
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	22 Apr 2021 20:02:49
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 20:02:30
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 20:02:30

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 12:01:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 12:01:50
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 12:01:13
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 12:00:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 12:00:50
	(b) (4)	
User closed query 'CDM-Coding: The trade name O2 System can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).		23 Apr 2021 12:00:45
Query 'CDM-Coding: The trade name O2 can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'updated.' (Site from System).	Brittany Belcher (b) (4)	23 Apr 2021 12:00:45
Data point term sent to Coder	System	23 Apr 2021 12:00:12
User entered 'Oxygen' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Apr 2021 11:59:40
User opened query 'CDM-Coding: The trade name O2 can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	23 Apr 2021 02:40:34
	(b) (4)	

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
' (Site from System).	System	22 Apr 2021 20:04:03
Data point term sent to Coder	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40
User entered 'O2'		

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'COPD'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '2'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Liters'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Continuous'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '11 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 20:03:40

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: OTHER GYNECOLOGICALS, ATC: OTHER GYNECOLOGICALS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:41:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:41:43
Data point term sent to Coder	System	22 Apr 2021 20:05:04
User entered 'Paroxetine'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Menopause'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '40'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '07 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 20:04:13

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:06:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:06:09
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:05:04
User entered 'Victoza'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Diabetes Type II'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '1.8'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '11 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 20:04:48

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:07:01
User coded data point as Term Coded data point by	Coder Import (b) (4)	22 Apr 2021 20:07:01
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:06:06
User entered 'Hydralazine'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User entered empty.	System	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User entered empty.	System	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:30
User entered empty.	System	22 Apr 2021 20:05:26

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:08:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:08:04
Data point term sent to Coder	System	22 Apr 2021 20:07:07
User entered 'Lisinopril'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '20'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User entered '1'	System	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User entered '1'	System	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:55
User entered '804 (804)'	System	22 Apr 2021 20:06:09

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 05:06:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 05:06:45
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:08:08
User entered 'Sodium Chloride (0.9% Infusion)'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'CVA'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '100'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mL (mL)'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Continuous'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User entered empty.	System	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User entered empty.	System	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:38
User entered empty.	System	22 Apr 2021 20:07:17

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
	(b) (4)	
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: DIAGNOSTIC AGENTS, ATC: OTHER DIAGNOSTIC AGENTS, ATC: TUBERCULOSIS DIAGNOSTICS, PRODUCT: TUBERCULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 05:06:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 05:06:45
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:08:09
User entered 'Tuberculin Injection'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06
	(b) (4)	
	(b) (4)	

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'TB Skin Test'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '5'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'IU (IU)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Intradermal'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User entered empty.	System	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User entered empty.	System	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:03
User entered empty.	System	22 Apr 2021 20:08:06

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
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)	23 Apr 2021 02:08:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:08:46
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:09:10
User entered 'Heparin Injection'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'DVT Prophylaxis'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '5,000'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'IU (IU)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'q 8 hours'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '07 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User entered empty.	System	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User entered empty.	System	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:25
User entered empty.	System	22 Apr 2021 20:08:57

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:10:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:10:55
	(b) (4)	
Data point term sent to Coder User entered 'Lisinopril'	System	22 Apr 2021 20:10:13
	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '08 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User entered '1'	System	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User entered '1'	System	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
User entered '804 (804)'	System	22 Apr 2021 20:09:31

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: ALIMINARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:11:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:11:56
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:11:14
User entered 'Lantus'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Diabetes Type II'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '30'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'IU (IU)'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'q 12 hours'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '09 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User entered empty.	System	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User entered empty.	System	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:46
User entered empty.	System	22 Apr 2021 20:10:20

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: ALIMINARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:12:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 20:12:58
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:12:14
User entered 'Humalog'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Diabetes Type II'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0-14'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'IU (IU)'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '4 times before meals and nightly'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '10 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User entered empty.	System	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User entered empty.	System	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:53
User entered empty.	System	22 Apr 2021 20:11:14

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 20:12:58
User coded data point as Term Coded data point by	Coder Import (b) (4)	22 Apr 2021 20:12:58
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 20:12:14
User entered 'Hydralazine'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Hypertension'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '20'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'mg (mg)'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered empty.	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '0'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered '06 Mar 2021'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:19:15
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User entered empty.	System	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User entered empty.	System	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:02:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:11
User entered empty.	System	22 Apr 2021 20:12:04

US3302455

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:02:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:29:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:26:41
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:11:42

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'USA-US087-2021-MRNA-1273-P301000023'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Gregory'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Feldman'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '141 Harold Fleming Court'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Spartanburg'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '29303'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:59:12
User entered 'US'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 15:43:11
User entered '3'	System	23 Apr 2021 12:57:26
User entered '2'	System	18 Mar 2021 17:59:06
User entered '1'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'USA-US087-2021-MRNA-1273-P301000023'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Gregory'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Feldman'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '141 Harold Fleming Court'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Spartanburg'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '29303'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:59:12
User entered 'US'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 15:43:11
User entered '3'	System	23 Apr 2021 12:57:26
User entered '2'	System	18 Mar 2021 17:59:06
User entered '1'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '12/Mar/2021 09:58'	(b) (4) System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:30

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:59:12
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'USA-US087-2021-MRNA-1273-P301000023'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Gregory'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Feldman'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '141 Harold Fleming Court'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Spartanburg'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '29303'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:59:12
User entered 'US'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 15:43:11
User entered '3'	System	23 Apr 2021 12:57:26
User entered '2'	System	18 Mar 2021 17:59:06
User entered '1'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
User entered '18/Mar/2021 13:59'	(b) (4) System	18 Mar 2021 17:59:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:30

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:59:12
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 17:59:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'USA-US087-2021-MRNA-1273-P301000023'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Gregory'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Feldman'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '141 Harold Fleming Court'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Spartanburg'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '29303'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:59:12
User entered 'US'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 15:43:11
User entered '3'	System	23 Apr 2021 12:57:26
User entered '2'	System	18 Mar 2021 17:59:06
User entered '1'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:30

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:10:47
User entered '23/Apr/2021 05:57'	System	23 Apr 2021 12:57:26

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:30

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.

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:38:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 21:10:47
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 12:57:26

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'USA-US087-2021-MRNA-1273-P301000023'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Yes (Y)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'No (N)'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Gregory'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Feldman'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '141 Harold Fleming Court'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered 'Spartanburg'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:57:42
User entered '29303'	System	12 Mar 2021 14:56:14

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:26:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:59:12
User entered 'US'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 15:43:11
User entered '3'	System	23 Apr 2021 12:57:26
User entered '2'	System	18 Mar 2021 17:59:06
User entered '1'	System	12 Mar 2021 14:58:06

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:02:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:07:10
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
User entered '30/Apr/2021 11:43'	(b) (4) System	30 Apr 2021 15:43:11

US3302455

Folder: SAE USA-US087-2021-MRNA-1273-P301000023

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:02:30

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:07:10
User signature succeeded.	Gregory Feldman (b) (4)	30 Apr 2021 17:27:18
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 15:43:11