

US3462255 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:38:14

All time stamps listed in this document are displayed in GMT

US3462255

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:22:31

Generated On: 09 Jun 2021 17:38:14

Participant ID

US3462255

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

US3462255

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:41:28

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Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:41:28

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:41:28

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Condition	DIABETES MELLITUS (TYPE 2)
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	SEASONAL ALLERGIC RHINITIS / PERENNIAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	OCCASIONAL TACHYCARDIA
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 (5)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	GASTROESOPHOGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	BILATERAL CARPEL TUNNEL
Start date (dd MMM yyyy)	UN UNK 1985
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	TORN RIGHT LATERAL MENISCUS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	ANXIETY
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 (11)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	LOWER BACK PAIN
Start date (dd MMM yyyy)	UN JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	BILATERAL CARPEL TUNNEL REPAIR
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Condition	RIGHT LATERAL MENISCUS REPAIR
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:53 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:53
Height (<i>xxx.x</i>)	165 cm
Weight (<i>xxx.x</i>)	105 kg
BMI (<i>xxx.x</i>)	38.56749 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Date of assessment (dd MMM yyyy) 19 AUG 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) UN UNK 1988

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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) 13 Feb 2021 01:41:28

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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) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 144306

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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)	19 AUG 2020
Time of assessment (00:00-23:59)	13:53 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:53
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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)	19 AUG 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:10
Temperature (xxx.x)	99 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 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: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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 AUG 2020

What was the treatment time? (00:00-23:59) 14:38 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 14:38

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	14:33 (24 HR)
Collection date and time (derived)	19 AUG 2020 14:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:30	19 AUG 2020 14:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 15:12

PC Open Date & Time

19 AUG 2020 14:58

PC Close Date & Time

19 AUG 2020 17:28

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	19 AUG 2020 18:41
PC Open Date & Time	19 AUG 2020 18:23
PC Close Date & Time	20 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 17:14

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 20:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 17:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 17:14

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 16:33

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 03:18

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 15:10

PC Open Date & Time

19 AUG 2020 14:58

PC Close Date & Time

19 AUG 2020 17:28

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 18:39

PC Open Date & Time

19 AUG 2020 18:23

PC Close Date & Time

20 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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 AUG 2020 17:14

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

21 AUG 2020 20:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 17:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 17:15

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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 AUG 2020 16:33

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

26 AUG 2020 03:19

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 15:11
PC Open Date & Time	19 AUG 2020 14:58
PC Close Date & Time	19 AUG 2020 17:28

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 18:40
PC Open Date & Time	19 AUG 2020 18:23
PC Close Date & Time	20 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:15
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2387

EAB) (1725)

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

62 of 2387

EAB) (1725)

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 17:01
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 17:15
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 16:34
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 03:19
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3462255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	13:14 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 13:14
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	14:16 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:16
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3462255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

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.

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 SEP 2020

What was the treatment time? (00:00-23:59) 13:44 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 13:44

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

US3462255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

14:16 (24 HR)

Collection date and time (derived)

16 SEP 2020 14:16

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:31	16 SEP 2020 13:31
Nasopharyngeal Swab 2	No		

US3462255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

16 SEP 2020 14:20

PC Open Date & Time

16 SEP 2020 14:04

PC Close Date & Time

16 SEP 2020 16:34

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	16 SEP 2020 18:06
PC Open Date & Time	16 SEP 2020 17:29
PC Close Date & Time	17 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 18:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 18:42

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 19:35

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 17:26

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 18:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 17:23

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 14:21

PC Open Date & Time

16 SEP 2020 14:04

PC Close Date & Time

16 SEP 2020 16:34

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:06

PC Open Date & Time

16 SEP 2020 17:29

PC Close Date & Time

17 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 18:34

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 18:41

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 19:35

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 17:27

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 18:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 17:24

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 14:22
PC Open Date & Time	16 SEP 2020 14:04
PC Close Date & Time	16 SEP 2020 16:34

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 18:08
PC Open Date & Time	16 SEP 2020 17:29
PC Close Date & Time	17 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 18:34
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 18:41
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

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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US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

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)

110 of 2387

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 17:27
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

112 of 2387

EAB) (1725)

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 18:24
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 17:24
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3462255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:28

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3462255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

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.

US3462255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

14 OCT 2020 13:40

US3462255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:41:29

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	19 OCT 2020 08:10:24
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 12:02:17

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 03:44:56

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 14:53:45
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 NOV 2020 13:18:43
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 DEC 2020 03:52:24
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Have 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 DEC 2020 03:38:18
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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	18 DEC 2020 03:43:37
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 07:18:26

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

04 JAN 2021 18:01:29

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 12:49:21

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 12:01:33

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

22 JAN 2021 05:23:57

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 13:00:37
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 03:27:41

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:43:06
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 <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	21 FEB 2021 08:55:33
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 15:53:39

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

05 MAR 2021 13:23:00

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

12 MAR 2021 00:22:16

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

19 MAR 2021 03:54:15

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

26 MAR 2021 11:35:31

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 05:23:31

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 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	11 APR 2021 14:08:54
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 06:54:38

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 08:13:00

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 <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	30 APR 2021 04:19:29
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 <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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 <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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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="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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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="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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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°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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 516

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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="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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	11 OCT 2022 23:59
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US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3462255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:38:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	Yes	27 FEB 2021 15:54:13

US3462255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:22:31

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:22:31

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:27:31

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:27:31

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:27:31

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 00:45:25

Generated On: 09 Jun 2021 17:38:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 13:18
Temperature (xxx.x)	98 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)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3462255

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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.

US3462255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	04 MAR 2021 13:40

US3462255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 18:18:48

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462255

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462255

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:38:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3462255

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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	UNBLND_DECIDE

US3462255

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Date of updated informed consent (<i>dd MMM yyyy</i>)	05 FEB 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>)	05 FEB 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

US3462255

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Height	165 cm
Weight	83.5 kg
BMI (xxx.x)	30.67034

US3462255

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Height	165 cm
Weight	83.5 kg
BMI (xxx.x)	30.67034
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)	05 FEB 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 11:50
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3462255

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Height	165 cm
Weight	83.5 kg
BMI (xxx.x)	30.67034
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)	05 FEB 2021
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 12:40
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3462255

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

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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.

US3462255

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

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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) 05 FEB 2021

What was the treatment time? (00:00-23:59) 12:10 (24 HR)

Treatment Date and Time (derived) 05 FEB 2021 12:10

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

US3462255

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 19:43:51

Generated On: 09 Jun 2021 17:38:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 FEB 2021

Collection time (00:00-23:59)

11:30 (24 HR)

Collection date and time (derived)

05 FEB 2021 11:30

US3462255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 FEB 2021
Collection time (00:00 - 23:59)	11:20
Collection Date and Time (derived)	05 FEB 2021 11:20

US3462255

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

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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

US3462255

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	OLD29

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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)	04 MAR 2021
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 13:18
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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)	04 MAR 2021
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 14:18
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3462255

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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.

US3462255

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

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) 04 MAR 2021

What was the treatment time? (00:00-23:59) 13:45 (24 HR)

Treatment Date and Time (derived) 04 MAR 2021 13:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3462255

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:14:32

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 16:14:58

Generated On: 09 Jun 2021 17:38:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 16:14:58

Generated On: 09 Jun 2021 17:38:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:21:43

Generated On: 09 Jun 2021 17:38:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 18:21:43

Generated On: 09 Jun 2021 17:38:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:21:43

Generated On: 09 Jun 2021 17:38:14

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) 05 Apr 2021 18:21:43

Generated On: 09 Jun 2021 17:38:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 APR 2021
Collection time (<i>00:00-23:59</i>)	12:45 (24 HR)
Collection date and time (derived)	01 APR 2021 12:45

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:22:31

Generated On: 09 Jun 2021 17:38:14

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

AEID	USA-US093-2020-MRNA-1273-P30 1000008
Adverse event	DEHYDRATION
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)	9 OCT 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	9 OCT 2020 08:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 OCT 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	17 OCT 2020 12:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	17 OCT 2020
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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

57 YEAR OLD FEMALE WITH
HYPERTENSION, TYPE II
DIABETES, GERD, AND
HISTORY OF GASTRIC BYPASS
SURGERY ON 02OCT2020.
SUBJECT WOKE UP 16OCT2020
WITH INCREASED FATIGUE
AND MALAISE. THOSE
SYMPTOMS HAD BEEN
ONGOING FOR
APPROXIMATELY ONE WEEK
PRIOR, BUT SUDDENLY
WORSENER. SUBJECT WENT TO
EMERGENCY DEPARTMENT
MORNING OF 16OCT2020 AT
APPROXIMATELY 09:30 AND
WAS DIAGNOSED WITH
SEVERE DEHYDRATION AND
ANEMIA. SUBJECT WAS
TREATED WITH IV FLUIDS AND
IRON SUPPLEMENTATION.
SUBJECT WAS ADMITTED TO
MONITOR KIDNEY FUNCTION.
SYMPTOMS IMPROVED WITH
TREATMENTS. SUBJECT WAS
DISCHARGED 17OCT2020 AT
APPROXIMATELY 12:00 WITH
INSTRUCTIONS TO TAKE OVER
THE COUNTER IRON
SUPPLEMENTATION.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

AEID	USA-US093-2020-MRNA-1273-P30 1000008
Adverse event	ANEMIA
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)	9 OCT 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	9 OCT 2020 08:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	17 OCT 2020
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 (2)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

57 YEAR OLD FEMALE WITH
HYPERTENSION, TYPE II
DIABETES, GERD, AND
HISTORY OF GASTRIC BYPASS
SURGERY ON 02OCT2020.
SUBJECT WOKE UP 16OCT2020
WITH INCREASED FATIGUE
AND MALAISE. THOSE
SYMPTOMS HAD BEEN
ONGOING FOR
APPROXIMATELY ONE WEEK
PRIOR, BUT SUDDENLY
WORSENER. SUBJECT WENT TO
EMERGENCY DEPARTMENT
MORNING OF 16OCT2020 AT
APPROXIMATELY 09:30 AND
WAS DIAGNOSED WITH
SEVERE DEHYDRATION AND
ANEMIA. SUBJECT WAS
TREATED WITH IV FLUIDS AND
IRON SUPPLEMENTATION.
SUBJECT WAS ADMITTED TO
MONITOR KIDNEY FUNCTION.
SYMPTOMS IMPROVED WITH
TREATMENTS. SUBJECT WAS
DISCHARGED 17OCT2020 AT
APPROXIMATELY 12:00 WITH
INSTRUCTIONS TO TAKE OVER
THE COUNTER IRON
SUPPLEMENTATION.

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 20:22:31

Generated On: 09 Jun 2021 17:38:14

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication HYDROCHLORATHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 15

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 1000

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL TACHYCARDIA

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 (4)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication OMEPRAZOLE

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 (5)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	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 1995
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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC RISK

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	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 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (7)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (10)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE ARTHRITIS

Dose per administration 300

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

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 (11)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	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 JAN 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)	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 (12)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication ALLERTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC RHINITIS
/ PERENNIAL ALLERGIC
RHINITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication	IRON SUPPLEMENT
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANEMIA
Dose per administration	325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input checked="" type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication VICODIN (325/5 MG)

Prophylaxis Yes ☐
No ☒

Indication POST GASTRIC BYPASS
SURGERY PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	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)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 1500

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	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 FEB 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

Name of Medication DERMAL FILLER

Prophylaxis Yes ☒
No ☐

Indication COSMETIC

Dose per administration UKN

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) 03 May 2021 18:18:47

Generated On: 09 Jun 2021 17:38:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2018		
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 20:22:31

Generated On: 09 Jun 2021 17:38:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 20:22:31

Generated On: 09 Jun 2021 17:38:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	GASTRIC BYPASS SURGERY	Medical History	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:38:14

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:38:14

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 ☐

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 18:18:48

Generated On: 09 Jun 2021 17:38:14

SAEID	USA-US093-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 18:18:48

Generated On: 09 Jun 2021 17:38:14

SAEID	USA-US093-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 21:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 18:18:48

Generated On: 09 Jun 2021 17:38:14

SAEID	USA-US093-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 18:18:48

Generated On: 09 Jun 2021 17:38:14

SAEID	USA-US093-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	29/APR/2021 17:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 18:18:48

Generated On: 09 Jun 2021 17:38:14

SAEID	USA-US093-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/MAY/2021 13:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3462255 (Prod: Crisor, LLC)

US3462255

Form: Participant Creation

Generated On: 09 Jun 2021 17:38:14

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
User entered 'US3462255'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:44:28

US3462255

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:23

US3462255

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:44:29

US3462255

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:23

US3462255

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'SCRN'	System	19 Aug 2020 21:52:23

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:44:30

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '57'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'YEARS'	System	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '57'	System	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Female (F)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'I'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	Danuel Hamlin (b) (4)	19 Aug 2020 21:52:45

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Aug 2020'	System	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2020'	System	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Amendment 2 (2)'	Danuel Hamlin (b) (4)	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:11

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:44:29

US3462255

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:38:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'I'	System	19 Aug 2020 21:53:20

US3462255

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:38:14

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:20

US3462255

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:38:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:03:31

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
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)	20 Aug 2020 21:48:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 21:48:24
Data point term sent to Coder	System	20 Aug 2020 19:04:38
User entered 'Diabetes mellitus (type 2)'	(b) (4), (b) (6)	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2011'	System	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2011'	System	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:04:11

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 00:28:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 00:28:23
Data point term sent to Coder	System	21 Oct 2020 00:27:17
User closed query 'DM-Coding: Please expand the reported abbreviations, entering the full text as the reported term.' (Site from System).	System	21 Oct 2020 00:26:54
Query 'DM-Coding: Please expand the reported abbreviations, entering the full text as the reported term.' answered with 'Corrected' (Site from System).	Danuel Hamlin (b) (4)	21 Oct 2020 00:26:54
User entered 'Seasonal Allergic Rhinitis / Perennial Allergic Rhinitis' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	21 Oct 2020 00:26:49
User opened query 'DM-Coding: Please expand the reported abbreviations, entering the full text as the reported term.' (Site from System).	Coder Import (b) (4)	14 Oct 2020 12:47:27
Data point term sent to Coder	System	20 Aug 2020 19:04:39
User entered 'SAR/PAR'	(b) (4), (b) (6)	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1980'	System	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1980'	System	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:04:30

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:06:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:06:29
Data point term sent to Coder	System	20 Aug 2020 19:05:40
User entered 'hypertension'	(b) (4), (b) (6)	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1995'	System	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1995'	System	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:04:49

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 09:11:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 09:11:11
Data point term sent to Coder	System	06 Nov 2020 00:23:44
Coding entries removed.	Danuel Hamlin (b) (4)	06 Nov 2020 00:22:53
User entered 'OCCASIONAL TACHYCARDIA' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:22:53
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 09:36:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 09:36:12
Data point term sent to Coder	System	20 Aug 2020 19:05:41
User entered 'tachycardia (intermittent)'	(b) (4), (b) (6)	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2000'	System	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2000'	System	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:05:31

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:24:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:24:24
Data point term sent to Coder	System	06 Nov 2020 00:23:44
Coding entries removed.	Daniel Hamlin (b) (4)	06 Nov 2020 00:23:19
User entered 'GASTROESOPHOGEAL REFLUX DISEASE' reason for change: Data Entry Error	Daniel Hamlin (b) (4)	06 Nov 2020 00:23:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:07:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:07:20
Data point term sent to Coder	System	20 Aug 2020 19:06:42
User entered 'GERD'	(b) (4), (b) (6)	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1995'	System	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1995'	System	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:05:59

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
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)	20 Aug 2020 19:13:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:13:20
Data point term sent to Coder	System	20 Aug 2020 19:11:53
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2010'	System	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2010'	System	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:11:04

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:13:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:13:20
Data point term sent to Coder	System	20 Aug 2020 19:11:55
User entered 'osteoarthritis (bilateral knees)'	(b) (4), (b) (6)	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2005'	System	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2005'	System	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:11:32

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:41:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:41:24
Data point term sent to Coder	System	06 Nov 2020 00:24:45
Coding entries removed.	Danuel Hamlin (b) (4)	06 Nov 2020 00:24:06
User entered 'BILATERAL CARPEL TUNNEL' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:24:06
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:13:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:13:21
Data point term sent to Coder	System	20 Aug 2020 19:12:56
User entered 'carpel tunnel syndrome'	(b) (4), (b) (6)	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1988'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1985'	System	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1985'	System	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1988'	System	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1988'	System	20 Aug 2020 19:11:59

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 10:10:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 10:10:48
Data point term sent to Coder	System	06 Nov 2020 00:24:45
Coding entries removed.	Daniel Hamlin (b) (4)	06 Nov 2020 00:24:38
User entered 'TORN RIGHT LATERAL MENISCUS' reason for change: Data Entry Error	Daniel Hamlin (b) (4)	06 Nov 2020 00:24:38
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 19:13:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 19:13:21
Data point term sent to Coder	System	20 Aug 2020 19:13:00
User entered 'meniscus tear'	(b) (4), (b) (6)	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2008'	(b) (4), (b) (6)	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2008'	System	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2008'	System	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2009'	System	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2009'	System	20 Aug 2020 19:12:54

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:15:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 19:15:26
Data point term sent to Coder	System	20 Aug 2020 19:14:01
User entered 'anxiety'	(b) (4), (b) (6)	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2000'	System	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2000'	System	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	20 Aug 2020 19:13:17

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 05:04:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 05:04:27
Data point term sent to Coder	System	21 Oct 2020 00:28:18
User entered 'Mild Obestiy'	Danuel Hamlin (b) (4)	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2010'	Danuel Hamlin (b) (4)	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2010'	System	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2010'	System	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	21 Oct 2020 00:27:51

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
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)	06 Nov 2020 00:27:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:27:27
Data point term sent to Coder	System	06 Nov 2020 00:26:46
User entered 'LOWER BACK PAIN'	Danuel Hamlin (b) (4)	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'UN Jul 2020'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	Danuel Hamlin (b) (4)	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jul 2020'	System	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2020'	System	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered empty.	System	06 Nov 2020 00:25:57

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:33:34
Data point term sent to Coder	System	06 Nov 2020 00:32:54
User entered 'Cesarean Section'	Danuel Hamlin (b) (4)	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1982'	Danuel Hamlin (b) (4)	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1982'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1982'	System	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1982'	System	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1982'	System	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1982'	System	06 Nov 2020 00:32:11

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:49:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:49:24
Data point term sent to Coder	System	06 Nov 2020 00:32:54
User entered 'CESAREAN SECTION'	Danuel Hamlin (b) (4)	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1988'	Danuel Hamlin (b) (4)	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1988'	Danuel Hamlin (b) (4)	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1988'	System	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1988'	System	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1988'	System	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1988'	System	06 Nov 2020 00:32:38

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:50:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:50:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:34:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:34:28
Data point term sent to Coder	System	06 Nov 2020 00:33:55
User entered 'Bilateral Carpel Tunnel Repair'	Danuel Hamlin (b) (4)	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1988'	Danuel Hamlin (b) (4)	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 1988'	Danuel Hamlin (b) (4)	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1988'	System	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1988'	System	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 1988'	System	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '1988'	System	06 Nov 2020 00:33:12

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:36:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:36:24
Data point term sent to Coder	System	06 Nov 2020 00:35:56
User entered 'Right Lateral Meniscus Repair'	Danuel Hamlin (b) (4)	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2009'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'un UNK 2009'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2009'	System	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2009'	System	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'Jan 2009'	System	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:38:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '2009'	System	06 Nov 2020 00:35:27

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '13:53'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered '19 Aug 2020 13:53'	System	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '165' cm	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:30
DataPoint set to visible.	System	19 Aug 2020 21:53:20

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '105' kg	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:30
DataPoint set to visible.	System	19 Aug 2020 21:53:20

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
Amendment Manager: User entered '38.56749'	System	17 Sep 2020 00:15:05
User entered '38.6'	System	20 Aug 2020 19:40:30
DataPoint set to visible.	System	19 Aug 2020 21:53:20

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'kg/m2'	System	20 Aug 2020 19:40:30
DataPoint set to visible.	System	19 Aug 2020 21:53:20

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:13:21
User entered '98.9' F		20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:13:21
User entered 'Other (Other)'		20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:13:21
User entered 'tympanic'		20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:13:21
User entered '84'		20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'bpm'	System	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:13:21
User entered '16'		20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'breaths/min'	System	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:13:21
User entered '126'		20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'mmHg'	System	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:13:21
User entered '76'		20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User entered 'mmHg'	System	20 Aug 2020 19:40:30

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47

US3462255

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:38

US3462255

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:23:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 21:05:41
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 19:40:38

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User closed query 'Per CDM RQ: Response noted. However, there is no corresponding procedure relating to child bearing potential within MH. Please review and update, else clarify. ' (Site from DM). Query 'Per CDM RQ: Response noted. However, there is no corresponding procedure relating to child bearing potential within MH. Please review and update, else clarify. ' answered with 'unknown' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:36:05
User opened query 'Per CDM RQ: Response noted. However, there is no corresponding procedure relating to child bearing potential within MH. Please review and update, else clarify. ' (Site from DM).		22 Feb 2021 21:46:37
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).		01 Dec 2020 19:12:15
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	18 Nov 2020 05:42:23
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 00:31:00
User entered 'Surgically sterile (SURGICALLY STERILE)'		09 Oct 2020 04:22:19
		20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'un UNK 1988' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:30:02
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '0' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 00:30:02
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:38:14

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:41:16

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:42:41

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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)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:38:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:42:41

US3462255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:40

US3462255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:40

US3462255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[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 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:53:40

US3462255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'VISIT1'	System	19 Aug 2020 21:53:40

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:59:28

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:43:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:43:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 20:59:28
User entered '144306' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:59:28

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:59:28

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

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 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:09:09
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 01:10:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	06 Nov 2020 01:09:39
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 14:25:21

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

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 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:09:39

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:09:39

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:09:39

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:09:39

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:14

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:09:39
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:38:11

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:22:10
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected.' (Site from DM).		04 Nov 2020 20:12:39
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 20:12:33
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		28 Sep 2020 10:54:33
User entered '165' cm		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:12:33
User entered '105' kg		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:22:10
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected.' (Site from DM).		04 Nov 2020 20:12:39
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 20:12:33
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		28 Sep 2020 10:54:33
User entered '165' cm		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:12:33
User entered '105' kg		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Pre-Dose (PREDOSE)'		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '13:53'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '19 Aug 2020 13:53'	System	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '98.9' F	(b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:03:03
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	20 Aug 2020 20:02:41
User entered 'Other (Other)'	(b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'tympanic' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:03:03
User entered empty.		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '84'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'bpm'	System	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16'	(b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'breaths/min'	System	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '126'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '76'	(b) (4), (b) (6)	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:22:10
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected.' (Site from DM).		04 Nov 2020 20:12:39
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 20:12:33
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		28 Sep 2020 10:54:33
User entered '165' cm		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:12:33
User entered '105' kg		20 Aug 2020 20:02:41

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Post-Dose (POSTDOSE)'		20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:43:24
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'c' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 20:04:21
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 20:04:06
User entered '15:10'	(b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '19 Aug 2020 15:10'	System	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '99' F	(b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'tympanic'	(b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '88'	(b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'bpm'	System	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16'	(b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'breaths/min'	System	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '140'	(b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '84'	(b) (4), (b) (6)	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	20 Aug 2020 20:04:06

US3462255

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 04:37:10
User entered 'Yes (Y)'		20 Aug 2020 20:04:37

US3462255

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 04:37:10
User entered '19 Aug 2020'		20 Aug 2020 20:04:37

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

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 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	Danuel Hamlin (b) (4)	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '14:38'	(b) (4) Danuel Hamlin (b) (4)	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '19 Aug 2020 14:38'	System	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Left Arm (LEFT ARM)'	Danuel Hamlin (b) (4)	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'ONCE'	System	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 21:54:26

US3462255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:12

US3462255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:12

US3462255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '14:33'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:12

US3462255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '19 Aug 2020 14:33'	System	20 Aug 2020 20:09:12

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:38:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '14:30'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '19 Aug 2020 14:30'	System	20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered empty.	System	20 Aug 2020 20:09:30

US3462255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:37

US3462255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	20 Aug 2020 20:09:37

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954' User entered 'Yes (Y)'	System	19 Aug 2020 22:12:26
	System	19 Aug 2020 22:12:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:12:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954'	System	19 Aug 2020 22:12:26
User entered '99.0'	System	19 Aug 2020 22:12:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:12:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954'	System	19 Aug 2020 22:12:26
User entered 'No (N)'	System	19 Aug 2020 22:12:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:12:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954'	System	19 Aug 2020 22:12:26
User entered '19 Aug 2020 15:12'	System	19 Aug 2020 22:12:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 14:58'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 17:28'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:49', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8' User entered 'Yes (Y)'	System	20 Aug 2020 01:41:26
	System	20 Aug 2020 01:41:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:41:07', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8' User entered '97.2'	System	20 Aug 2020 01:41:26
	System	20 Aug 2020 01:41:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:41:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8'	System	20 Aug 2020 01:41:26
User entered 'No (N)'	System	20 Aug 2020 01:41:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:41:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8'	System	20 Aug 2020 01:41:26
User entered '19 Aug 2020 18:41'	System	20 Aug 2020 01:41:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 18:23'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 2'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3'	System	21 Aug 2020 00:15:07
User entered 'Yes (Y)'	System	21 Aug 2020 00:15:07

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3' User entered '98.5'	System	21 Aug 2020 00:15:07
	System	21 Aug 2020 00:15:07

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3'	System	21 Aug 2020 00:15:07
User entered 'No (N)'	System	21 Aug 2020 00:15:07

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3'	System	21 Aug 2020 00:15:07
User entered '20 Aug 2020 17:14'	System	21 Aug 2020 00:15:07

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 3'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b' User entered 'Yes (Y)'	System	22 Aug 2020 03:21:39
	System	22 Aug 2020 03:21:39

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b' User entered '97.3'	System	22 Aug 2020 03:21:39
	System	22 Aug 2020 03:21:39

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b'	System	22 Aug 2020 03:21:39
User entered 'No (N)'	System	22 Aug 2020 03:21:39

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b'	System	22 Aug 2020 03:21:39
User entered '21 Aug 2020 20:21'	System	22 Aug 2020 03:21:39

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 4'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T16:59:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa' User entered 'Yes (Y)'	System	23 Aug 2020 00:00:13
	System	23 Aug 2020 00:00:13

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T16:59:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa' User entered '98.5'	System	23 Aug 2020 00:00:13
	System	23 Aug 2020 00:00:13

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa'	System	23 Aug 2020 00:00:13
User entered 'No (N)'	System	23 Aug 2020 00:00:13

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa'	System	23 Aug 2020 00:00:13
User entered '22 Aug 2020 17:00'	System	23 Aug 2020 00:00:13

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 5'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered 'Yes (Y)'	System	24 Aug 2020 00:14:44
	System	24 Aug 2020 00:14:44

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered '98.5'	System	24 Aug 2020 00:14:44
	System	24 Aug 2020 00:14:44

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered 'No (N)'	System	24 Aug 2020 00:14:44
	System	24 Aug 2020 00:14:44

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered '23 Aug 2020 17:14'	System	24 Aug 2020 00:14:44
	System	24 Aug 2020 00:14:44

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 6'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23' User entered 'Yes (Y)'	System	24 Aug 2020 23:33:40
	System	24 Aug 2020 23:33:40

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23' User entered '98.5'	System	24 Aug 2020 23:33:40
	System	24 Aug 2020 23:33:40

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23'	System	24 Aug 2020 23:33:40
User entered 'No (N)'	System	24 Aug 2020 23:33:40

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23' User entered '24 Aug 2020 16:33'	System	24 Aug 2020 23:33:40
	System	24 Aug 2020 23:33:40

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 7'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a' User entered 'Yes (Y)'	System	26 Aug 2020 10:18:48
	System	26 Aug 2020 10:18:48

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a' User entered '98.6'	System	26 Aug 2020 10:18:48
	System	26 Aug 2020 10:18:48

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a'	System	26 Aug 2020 10:18:48
User entered 'No (N)'	System	26 Aug 2020 10:18:48

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a' User entered '26 Aug 2020 03:18'	System	26 Aug 2020 10:18:48
	System	26 Aug 2020 10:18:48

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' User entered 'None (1)'	System	19 Aug 2020 22:11:04
	System	19 Aug 2020 22:11:04

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' User entered 'No (N)'	System	19 Aug 2020 22:11:04
	System	19 Aug 2020 22:11:04

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' User entered 'No (N)'	System	19 Aug 2020 22:11:04
	System	19 Aug 2020 22:11:04

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' User entered 'None (1)'	System	19 Aug 2020 22:11:04
	System	19 Aug 2020 22:11:04

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' User entered '19 Aug 2020 15:10'	System	19 Aug 2020 22:11:04
	System	19 Aug 2020 22:11:04

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 14:58'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 17:28'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' User entered 'None (1)'	System	20 Aug 2020 01:39:59
	System	20 Aug 2020 01:39:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' User entered 'No (N)'	System	20 Aug 2020 01:39:59
	System	20 Aug 2020 01:39:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' User entered 'No (N)'	System	20 Aug 2020 01:39:59
	System	20 Aug 2020 01:39:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:48', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' User entered 'None (1)'	System	20 Aug 2020 01:39:59
	System	20 Aug 2020 01:39:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:52', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' User entered '19 Aug 2020 18:39'	System	20 Aug 2020 01:39:59
	System	20 Aug 2020 01:39:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 18:23'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 2'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838' User entered 'None (1)'	System	21 Aug 2020 00:14:35
	System	21 Aug 2020 00:14:35

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838'	System	21 Aug 2020 00:14:35
User entered 'No (N)'	System	21 Aug 2020 00:14:35

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838'	System	21 Aug 2020 00:14:35
User entered 'No (N)'	System	21 Aug 2020 00:14:35

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838' User entered 'None (1)'	System	21 Aug 2020 00:14:35
	System	21 Aug 2020 00:14:35

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838'	System	21 Aug 2020 00:14:35
User entered '20 Aug 2020 17:14'	System	21 Aug 2020 00:14:35

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 3'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' User entered 'None (1)'	System	22 Aug 2020 03:21:59
	System	22 Aug 2020 03:21:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' User entered 'No (N)'	System	22 Aug 2020 03:21:59
	System	22 Aug 2020 03:21:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' User entered 'No (N)'	System	22 Aug 2020 03:21:59
	System	22 Aug 2020 03:21:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' User entered 'None (1)'	System	22 Aug 2020 03:21:59
	System	22 Aug 2020 03:21:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' User entered '21 Aug 2020 20:21'	System	22 Aug 2020 03:21:59
	System	22 Aug 2020 03:21:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 4'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337'	System	23 Aug 2020 00:00:56
User entered 'None (1)'	System	23 Aug 2020 00:00:56

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337'	System	23 Aug 2020 00:00:56
User entered 'No (N)'	System	23 Aug 2020 00:00:56

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337'	System	23 Aug 2020 00:00:56
User entered 'No (N)'	System	23 Aug 2020 00:00:56

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:49', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337' User entered 'None (1)'	System	23 Aug 2020 00:00:56
	System	23 Aug 2020 00:00:56

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:52', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337'	System	23 Aug 2020 00:00:56
User entered '22 Aug 2020 17:00'	System	23 Aug 2020 00:00:56

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 5'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2' User entered 'None (1)'	System	24 Aug 2020 00:15:08
	System	24 Aug 2020 00:15:08

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2'	System	24 Aug 2020 00:15:08
User entered 'No (N)'	System	24 Aug 2020 00:15:08

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2'	System	24 Aug 2020 00:15:08
User entered 'No (N)'	System	24 Aug 2020 00:15:08

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2' User entered 'None (1)'	System	24 Aug 2020 00:15:08
	System	24 Aug 2020 00:15:08

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2'	System	24 Aug 2020 00:15:08
User entered '23 Aug 2020 17:15'	System	24 Aug 2020 00:15:08

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 6'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' User entered 'None (1)'	System	24 Aug 2020 23:34:02
	System	24 Aug 2020 23:34:02

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9'	System	24 Aug 2020 23:34:02
User entered 'No (N)'	System	24 Aug 2020 23:34:02

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' User entered 'No (N)'	System	24 Aug 2020 23:34:02
	System	24 Aug 2020 23:34:02

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' User entered 'None (1)'	System	24 Aug 2020 23:34:02
	System	24 Aug 2020 23:34:02

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' User entered '24 Aug 2020 16:33'	System	24 Aug 2020 23:34:02
	System	24 Aug 2020 23:34:02

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 7'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered 'None (1)'	System	26 Aug 2020 10:19:11
	System	26 Aug 2020 10:19:11

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a'	System	26 Aug 2020 10:19:11
User entered 'No (N)'	System	26 Aug 2020 10:19:11

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered 'No (N)'	System	26 Aug 2020 10:19:11
	System	26 Aug 2020 10:19:11

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:02', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered 'None (1)'	System	26 Aug 2020 10:19:11
	System	26 Aug 2020 10:19:11

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered '26 Aug 2020 03:19'	System	26 Aug 2020 10:19:11
	System	26 Aug 2020 10:19:11

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:11', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' User entered 'None (0)'	System	19 Aug 2020 22:11:46
	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' User entered 'None (0)'	System	19 Aug 2020 22:11:46
	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' User entered 'None (0)'	System	19 Aug 2020 22:11:46
	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' User entered 'None (0)'	System	19 Aug 2020 22:11:46
	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' User entered 'None (0)'	System	19 Aug 2020 22:11:46
	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' User entered 'None (0)'	System	19 Aug 2020 22:11:46
	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b'	System	19 Aug 2020 22:11:46
User entered 'No (N)'	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' User entered '19 Aug 2020 15:11'	System	19 Aug 2020 22:11:46
	System	19 Aug 2020 22:11:46

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 14:58'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 17:28'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' User entered 'None (0)'	System	20 Aug 2020 01:40:50
	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' User entered 'None (0)'	System	20 Aug 2020 01:40:50
	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' User entered 'None (0)'	System	20 Aug 2020 01:40:50
	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' User entered 'None (0)'	System	20 Aug 2020 01:40:50
	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' User entered 'None (0)'	System	20 Aug 2020 01:40:50
	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' User entered 'None (0)'	System	20 Aug 2020 01:40:50
	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b'	System	20 Aug 2020 01:40:50
User entered 'No (N)'	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b'	System	20 Aug 2020 01:40:50
User entered '19 Aug 2020 18:40'	System	20 Aug 2020 01:40:50

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Aug 2020 18:23'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 2'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)'	System	21 Aug 2020 00:15:48
	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)'	System	21 Aug 2020 00:15:48
	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)'	System	21 Aug 2020 00:15:48
	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)'	System	21 Aug 2020 00:15:48
	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee'	System	21 Aug 2020 00:15:48
User entered 'None (0)'	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)'	System	21 Aug 2020 00:15:48
	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee'	System	21 Aug 2020 00:15:48
User entered 'No (N)'	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee'	System	21 Aug 2020 00:15:48
User entered '20 Aug 2020 17:15'	System	21 Aug 2020 00:15:48

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 3'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:01', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered 'None (0)'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered 'None (0)'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered 'None (0)'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered 'None (0)'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered 'None (0)'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebc5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered 'None (0)'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered 'No (N)'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410'	System	22 Aug 2020 03:22:32
User entered '21 Aug 2020 20:22'	System	22 Aug 2020 03:22:32

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 4'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'None (0)'	System	23 Aug 2020 00:02:12
	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e'	System	23 Aug 2020 00:02:12
User entered 'No interference with activity (1)'	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'No interference with activity (1)'	System	23 Aug 2020 00:02:12
	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:38', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e'	System	23 Aug 2020 00:02:12
User entered 'No interference with activity (1)'	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:42', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'None (0)'	System	23 Aug 2020 00:02:12
	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'None (0)'	System	23 Aug 2020 00:02:12
	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'No (N)'	System	23 Aug 2020 00:02:12
	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered '22 Aug 2020 17:01'	System	23 Aug 2020 00:02:12
	System	23 Aug 2020 00:02:12

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 5'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' User entered 'None (0)'	System	24 Aug 2020 00:15:37
	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' User entered 'None (0)'	System	24 Aug 2020 00:15:37
	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:16', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' User entered 'None (0)'	System	24 Aug 2020 00:15:37
	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' User entered 'None (0)'	System	24 Aug 2020 00:15:37
	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' User entered 'None (0)'	System	24 Aug 2020 00:15:37
	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' User entered 'None (0)'	System	24 Aug 2020 00:15:37
	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' User entered 'No (N)'	System	24 Aug 2020 00:15:37
	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a'	System	24 Aug 2020 00:15:37
User entered '23 Aug 2020 17:15'	System	24 Aug 2020 00:15:37

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 6'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138'	System	24 Aug 2020 23:34:44
User entered 'None (0)'	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138'	System	24 Aug 2020 23:34:44
User entered 'None (0)'	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:11', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138'	System	24 Aug 2020 23:34:44
User entered 'None (0)'	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138'	System	24 Aug 2020 23:34:44
User entered 'No interference with activity (1)'	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138'	System	24 Aug 2020 23:34:44
User entered 'None (0)'	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' User entered 'None (0)'	System	24 Aug 2020 23:34:44
	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138'	System	24 Aug 2020 23:34:44
User entered 'No (N)'	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138'	System	24 Aug 2020 23:34:44
User entered '24 Aug 2020 16:34'	System	24 Aug 2020 23:34:44

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 7'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c'	System	26 Aug 2020 10:19:41
User entered 'None (0)'	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c'	System	26 Aug 2020 10:19:41
User entered 'None (0)'	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' User entered 'None (0)'	System	26 Aug 2020 10:19:41
	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' User entered 'None (0)'	System	26 Aug 2020 10:19:41
	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c'	System	26 Aug 2020 10:19:41
User entered 'None (0)'	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c'	System	26 Aug 2020 10:19:41
User entered 'None (0)'	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c'	System	26 Aug 2020 10:19:41
User entered 'No (N)'	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c'	System	26 Aug 2020 10:19:41
User entered '26 Aug 2020 03:19'	System	26 Aug 2020 10:19:41

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 21:54:26

US3462255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:12

US3462255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '26 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:12

US3462255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:12

US3462255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:12

US3462255

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:19

US3462255

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	16 Sep 2020 21:04:19

US3462255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:35

US3462255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '02 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:35

US3462255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:35

US3462255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:35

US3462255

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:04:45

US3462255

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	16 Sep 2020 21:04:45

US3462255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:05:20

US3462255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '09 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:05:20

US3462255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:05:20

US3462255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:05:20

US3462255

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:05:27

US3462255

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	16 Sep 2020 21:05:27

US3462255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 02:45:46
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 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 'Added' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 01:10:31
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 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)	02 Nov 2020 08:48:10
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	16 Sep 2020 21:05:41

US3462255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:05:41

US3462255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[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 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:05:41

US3462255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'VISIT2'	System	16 Sep 2020 21:05:41

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '13:14'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '16 Sep 2020 13:14'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '97.3' F	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'TYMPANIC'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '90'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'bpm'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'breaths/min'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '130'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '74'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:27:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	24 Sep 2020 20:27:53
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:27:47
User entered empty.	Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '14:16'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '16 Sep 2020 14:16'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '98.9' F	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'TYMPANIC'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '90'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'bpm'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '18'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'breaths/min'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '124'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '78'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'mmHg'	System	24 Sep 2020 20:27:47

US3462255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:28:00

US3462255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:28:00

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

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 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	Danuel Hamlin (b) (4)	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '13:44'	(b) (4) Danuel Hamlin (b) (4)	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '16 Sep 2020 13:44'	System	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Left Arm (LEFT ARM)'	Danuel Hamlin (b) (4)	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'ONCE'	System	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 21:06:05

US3462255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:28:33

US3462255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	24 Sep 2020 20:28:46
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	24 Sep 2020 20:28:46
User entered '16 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	24 Sep 2020 20:28:46
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Sep 2020 20:28:33
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	24 Sep 2020 20:28:33

US3462255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '14:16'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:28:33

US3462255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '16 Sep 2020 14:16'	System	24 Sep 2020 20:28:46
User entered '14 Sep 2020 14:16'	System	24 Sep 2020 20:28:33

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:38:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '16 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '13:31'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '16 Sep 2020 13:31'	System	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Oct 2020 23:52:00
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Oct 2020 23:52:00
User entered '13:31'	Danuel Hamlin (b) (4)	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered empty.	System	11 Oct 2020 23:52:00
User entered '16 Sep 2020 13:31'	System	24 Sep 2020 20:29:14

US3462255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 20:29:19

US3462255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	24 Sep 2020 20:29:19

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449' User entered 'Yes (Y)'	System	16 Sep 2020 21:21:00
	System	16 Sep 2020 21:21:00

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449' User entered '98.9'	System	16 Sep 2020 21:21:00
	System	16 Sep 2020 21:21:00

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449'	System	16 Sep 2020 21:21:00
User entered 'No (N)'	System	16 Sep 2020 21:21:00

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449'	System	16 Sep 2020 21:21:00
User entered '16 Sep 2020 14:20'	System	16 Sep 2020 21:21:00

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 14:04'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 16:34'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:05:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' User entered 'Yes (Y)'	System	17 Sep 2020 01:06:16
	System	17 Sep 2020 01:06:16

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:05:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' User entered '98.6'	System	17 Sep 2020 01:06:16
	System	17 Sep 2020 01:06:16

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' User entered 'No (N)'	System	17 Sep 2020 01:06:16
	System	17 Sep 2020 01:06:16

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' User entered '16 Sep 2020 18:06'	System	17 Sep 2020 01:06:16
	System	17 Sep 2020 01:06:16

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 17:29'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 2'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104' User entered 'Yes (Y)'	System	18 Sep 2020 01:33:53
	System	18 Sep 2020 01:33:53

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:42', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104' User entered '98.6'	System	18 Sep 2020 01:33:53
	System	18 Sep 2020 01:33:53

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104'	System	18 Sep 2020 01:33:53
User entered 'No (N)'	System	18 Sep 2020 01:33:53

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104'	System	18 Sep 2020 01:33:53
User entered '17 Sep 2020 18:33'	System	18 Sep 2020 01:33:53

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 3'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:07', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d' User entered 'Yes (Y)'	System	19 Sep 2020 01:42:28
	System	19 Sep 2020 01:42:28

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d' User entered '98.2'	System	19 Sep 2020 01:42:28
	System	19 Sep 2020 01:42:28

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d'	System	19 Sep 2020 01:42:28
User entered 'No (N)'	System	19 Sep 2020 01:42:28

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d'	System	19 Sep 2020 01:42:28
User entered '18 Sep 2020 18:42'	System	19 Sep 2020 01:42:28

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 4'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:34:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' User entered 'Yes (Y)'	System	20 Sep 2020 02:35:09
	System	20 Sep 2020 02:35:09

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:34:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' User entered '98.5'	System	20 Sep 2020 02:35:09
	System	20 Sep 2020 02:35:09

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' User entered 'No (N)'	System	20 Sep 2020 02:35:09
	System	20 Sep 2020 02:35:09

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' User entered '19 Sep 2020 19:35'	System	20 Sep 2020 02:35:09
	System	20 Sep 2020 02:35:09

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 5'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe' User entered 'Yes (Y)'	System	21 Sep 2020 00:26:43
	System	21 Sep 2020 00:26:43

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe' User entered '98.2'	System	21 Sep 2020 00:26:43
	System	21 Sep 2020 00:26:43

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe'	System	21 Sep 2020 00:26:43
User entered 'No (N)'	System	21 Sep 2020 00:26:43

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe'	System	21 Sep 2020 00:26:43
User entered '20 Sep 2020 17:26'	System	21 Sep 2020 00:26:43

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 6'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:23:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' User entered 'Yes (Y)'	System	22 Sep 2020 01:24:04
	System	22 Sep 2020 01:24:04

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:23:52', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' User entered '98.6'	System	22 Sep 2020 01:24:04
	System	22 Sep 2020 01:24:04

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:23:57', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' User entered 'No (N)'	System	22 Sep 2020 01:24:04
	System	22 Sep 2020 01:24:04

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' User entered '21 Sep 2020 18:24'	System	22 Sep 2020 01:24:04
	System	22 Sep 2020 01:24:04

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 7'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204' User entered 'Yes (Y)'	System	23 Sep 2020 00:23:39
	System	23 Sep 2020 00:23:39

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204' User entered '96.5'	System	23 Sep 2020 00:23:39
	System	23 Sep 2020 00:23:39

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204'	System	23 Sep 2020 00:23:39
User entered 'No (N)'	System	23 Sep 2020 00:23:39

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204'	System	23 Sep 2020 00:23:39
User entered '22 Sep 2020 17:23'	System	23 Sep 2020 00:23:39

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered 'None (1)'	System	16 Sep 2020 21:21:35
	System	16 Sep 2020 21:21:35

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered 'No (N)'	System	16 Sep 2020 21:21:35
	System	16 Sep 2020 21:21:35

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered 'No (N)'	System	16 Sep 2020 21:21:35
	System	16 Sep 2020 21:21:35

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered 'None (1)'	System	16 Sep 2020 21:21:35
	System	16 Sep 2020 21:21:35

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered '16 Sep 2020 14:21'	System	16 Sep 2020 21:21:35
	System	16 Sep 2020 21:21:35

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 14:04'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 16:34'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447' User entered 'None (1)'	System	17 Sep 2020 01:06:52
	System	17 Sep 2020 01:06:52

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447'	System	17 Sep 2020 01:06:52
User entered 'No (N)'	System	17 Sep 2020 01:06:52

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447'	System	17 Sep 2020 01:06:52
User entered 'No (N)'	System	17 Sep 2020 01:06:52

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447' User entered 'None (1)'	System	17 Sep 2020 01:06:52
	System	17 Sep 2020 01:06:52

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447'	System	17 Sep 2020 01:06:52
User entered '16 Sep 2020 18:06'	System	17 Sep 2020 01:06:52

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 17:29'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 2'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' User entered 'None (1)'	System	18 Sep 2020 01:34:18
	System	18 Sep 2020 01:34:18

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' User entered 'No (N)'	System	18 Sep 2020 01:34:18
	System	18 Sep 2020 01:34:18

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' User entered 'No (N)'	System	18 Sep 2020 01:34:18
	System	18 Sep 2020 01:34:18

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' User entered 'None (1)'	System	18 Sep 2020 01:34:18
	System	18 Sep 2020 01:34:18

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' User entered '17 Sep 2020 18:34'	System	18 Sep 2020 01:34:18
	System	18 Sep 2020 01:34:18

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 3'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2'	System	19 Sep 2020 01:42:02
User entered 'None (1)'	System	19 Sep 2020 01:42:02

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2'	System	19 Sep 2020 01:42:02
User entered 'No (N)'	System	19 Sep 2020 01:42:02

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2'	System	19 Sep 2020 01:42:02
User entered 'No (N)'	System	19 Sep 2020 01:42:02

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2'	System	19 Sep 2020 01:42:02
User entered 'None (1)'	System	19 Sep 2020 01:42:02

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2'	System	19 Sep 2020 01:42:02
User entered '18 Sep 2020 18:41'	System	19 Sep 2020 01:42:02

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 4'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37' User entered 'None (1)'	System	20 Sep 2020 02:35:30
	System	20 Sep 2020 02:35:30

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:14', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37'	System	20 Sep 2020 02:35:30
User entered 'No (N)'	System	20 Sep 2020 02:35:30

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37'	System	20 Sep 2020 02:35:30
User entered 'No (N)'	System	20 Sep 2020 02:35:30

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37' User entered 'None (1)'	System	20 Sep 2020 02:35:30
	System	20 Sep 2020 02:35:30

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37'	System	20 Sep 2020 02:35:30
User entered '19 Sep 2020 19:35'	System	20 Sep 2020 02:35:30

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 5'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2'	System	21 Sep 2020 00:27:07
User entered 'None (1)'	System	21 Sep 2020 00:27:07

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2'	System	21 Sep 2020 00:27:07
User entered 'No (N)'	System	21 Sep 2020 00:27:07

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2'	System	21 Sep 2020 00:27:07
User entered 'No (N)'	System	21 Sep 2020 00:27:07

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2' User entered 'None (1)'	System	21 Sep 2020 00:27:07
	System	21 Sep 2020 00:27:07

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2'	System	21 Sep 2020 00:27:07
User entered '20 Sep 2020 17:27'	System	21 Sep 2020 00:27:07

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 6'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' User entered 'None (1)'	System	22 Sep 2020 01:24:25
	System	22 Sep 2020 01:24:25

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' User entered 'No (N)'	System	22 Sep 2020 01:24:25
	System	22 Sep 2020 01:24:25

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' User entered 'No (N)'	System	22 Sep 2020 01:24:25
	System	22 Sep 2020 01:24:25

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:16', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' User entered 'None (1)'	System	22 Sep 2020 01:24:25
	System	22 Sep 2020 01:24:25

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20'	System	22 Sep 2020 01:24:25
User entered '21 Sep 2020 18:24'	System	22 Sep 2020 01:24:25

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 7'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:39', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b'	System	23 Sep 2020 00:24:08
User entered 'None (1)'	System	23 Sep 2020 00:24:08

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' User entered 'No (N)'	System	23 Sep 2020 00:24:08
	System	23 Sep 2020 00:24:08

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' User entered 'No (N)'	System	23 Sep 2020 00:24:08
	System	23 Sep 2020 00:24:08

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' User entered 'None (1)'	System	23 Sep 2020 00:24:08
	System	23 Sep 2020 00:24:08

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b'	System	23 Sep 2020 00:24:08
User entered '22 Sep 2020 17:24'	System	23 Sep 2020 00:24:08

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:39', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'No (N)'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:22:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered '16 Sep 2020 14:22'	System	16 Sep 2020 21:22:06
	System	16 Sep 2020 21:22:06

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 14:04'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 16:34'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'None (0)'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'None (0)'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'None (0)'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'None (0)'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'None (0)'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'None (0)'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:08:01', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'No (N)'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:08:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered '16 Sep 2020 18:08'	System	17 Sep 2020 01:08:08
	System	17 Sep 2020 01:08:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '16 Sep 2020 17:29'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 2'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' User entered 'None (0)'	System	18 Sep 2020 01:34:52
	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' User entered 'None (0)'	System	18 Sep 2020 01:34:52
	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' User entered 'None (0)'	System	18 Sep 2020 01:34:52
	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' User entered 'None (0)'	System	18 Sep 2020 01:34:52
	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' User entered 'None (0)'	System	18 Sep 2020 01:34:52
	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' User entered 'None (0)'	System	18 Sep 2020 01:34:52
	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' User entered 'No (N)'	System	18 Sep 2020 01:34:52
	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372'	System	18 Sep 2020 01:34:52
User entered '17 Sep 2020 18:34'	System	18 Sep 2020 01:34:52

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 3'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:07', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' User entered 'None (0)'	System	19 Sep 2020 01:41:38
	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93'	System	19 Sep 2020 01:41:38
User entered 'None (0)'	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:16', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' User entered 'None (0)'	System	19 Sep 2020 01:41:38
	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' User entered 'None (0)'	System	19 Sep 2020 01:41:38
	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' User entered 'None (0)'	System	19 Sep 2020 01:41:38
	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93'	System	19 Sep 2020 01:41:38
User entered 'None (0)'	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93'	System	19 Sep 2020 01:41:38
User entered 'No (N)'	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93'	System	19 Sep 2020 01:41:38
User entered '18 Sep 2020 18:41'	System	19 Sep 2020 01:41:38

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 4'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:38', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered 'None (0)'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered 'None (0)'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:48', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered 'None (0)'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered 'None (0)'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:53', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered 'None (0)'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered 'None (0)'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:36:02', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered 'No (N)'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:36:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2'	System	20 Sep 2020 02:36:09
User entered '19 Sep 2020 19:36'	System	20 Sep 2020 02:36:09

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 5'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040'	System	21 Sep 2020 00:27:44
User entered 'None (0)'	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040'	System	21 Sep 2020 00:27:44
User entered 'None (0)'	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' User entered 'None (0)'	System	21 Sep 2020 00:27:44
	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' User entered 'None (0)'	System	21 Sep 2020 00:27:44
	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040'	System	21 Sep 2020 00:27:44
User entered 'None (0)'	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' User entered 'None (0)'	System	21 Sep 2020 00:27:44
	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040'	System	21 Sep 2020 00:27:44
User entered 'No (N)'	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040'	System	21 Sep 2020 00:27:44
User entered '20 Sep 2020 17:27'	System	21 Sep 2020 00:27:44

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 6'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)'	System	22 Sep 2020 01:25:08
	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)'	System	22 Sep 2020 01:25:08
	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)'	System	22 Sep 2020 01:25:08
	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)'	System	22 Sep 2020 01:25:08
	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)'	System	22 Sep 2020 01:25:08
	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:38', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)'	System	22 Sep 2020 01:25:08
	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:42', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec'	System	22 Sep 2020 01:25:08
User entered 'No (N)'	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec'	System	22 Sep 2020 01:25:08
User entered '21 Sep 2020 18:24'	System	22 Sep 2020 01:25:08

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	16 Sep 2020 21:06:05
User entered 'Day 7'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' User entered 'None (0)'	System	23 Sep 2020 00:24:39
	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:14', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' User entered 'None (0)'	System	23 Sep 2020 00:24:39
	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' User entered 'None (0)'	System	23 Sep 2020 00:24:39
	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' User entered 'None (0)'	System	23 Sep 2020 00:24:39
	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287'	System	23 Sep 2020 00:24:39
User entered 'None (0)'	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' User entered 'None (0)'	System	23 Sep 2020 00:24:39
	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287'	System	23 Sep 2020 00:24:39
User entered 'No (N)'	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287'	System	23 Sep 2020 00:24:39
User entered '22 Sep 2020 17:24'	System	23 Sep 2020 00:24:39

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 21:06:05

US3462255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:38:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 21:06:05

US3462255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:10:55

US3462255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '23 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:10:55

US3462255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:10:55

US3462255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:10:55

US3462255

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:12

US3462255

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	06 Nov 2020 01:11:12

US3462255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:30

US3462255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '30 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:30

US3462255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:30

US3462255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:30

US3462255

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:42

US3462255

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	06 Nov 2020 01:11:42

US3462255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:53

US3462255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '07 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:53

US3462255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:53

US3462255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:11:53

US3462255

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:04

US3462255

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	06 Nov 2020 01:12:04

US3462255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:21

US3462255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '14 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:21

US3462255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[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 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:21

US3462255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'VISIT3'	System	06 Nov 2020 01:12:21

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered empty.	System	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered empty.	System	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered empty.	System	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered empty.	System	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered empty.	System	06 Nov 2020 01:12:54

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52

US3462255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:59

US3462255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:12:59

US3462255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:13:14

US3462255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '14 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:13:14

US3462255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered '13:40'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:13:14

US3462255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered '14 Oct 2020 13:40'	System	06 Nov 2020 01:13:14

US3462255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:41:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	06 Nov 2020 01:13:18

US3462255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	06 Nov 2020 01:13:18

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 64'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:08', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83'	System	19 Oct 2020 15:11:03
User entered 'Yes (Y)'	System	19 Oct 2020 15:11:03

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83'	System	19 Oct 2020 15:11:03
User entered 'No (N)'	System	19 Oct 2020 15:11:03

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83'	System	19 Oct 2020 15:11:03
User entered 'No (N)'	System	19 Oct 2020 15:11:03

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83'	System	19 Oct 2020 15:11:03
User entered 'Yes (Y)'	System	19 Oct 2020 15:11:03

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:10:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83'	System	19 Oct 2020 15:11:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Oct 2020 15:11:03

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:10:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83' User entered '19 Oct 2020 08:10:24'	System	19 Oct 2020 15:11:03
	System	19 Oct 2020 15:11:03

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 71'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-28T12:02:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9da81764-7151-46dd-952d-4f9299bcb2a2'	System	28 Oct 2020 19:02:20
User entered 'No (N)'	System	28 Oct 2020 19:02:20

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-28T12:02:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9da81764-7151-46dd-952d-4f9299bcb2a2'	System	28 Oct 2020 19:02:20
User entered 'No (N)'	System	28 Oct 2020 19:02:20

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-28T12:02:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9da81764-7151-46dd-952d-4f9299bcb2a2' User entered '28 Oct 2020 12:02:17'	System	28 Oct 2020 19:02:20
	System	28 Oct 2020 19:02:20

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 78'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-11-02T03:44:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '15766665-e07a-4e27-801b-948695b7ea50'	System	02 Nov 2020 11:45:00
User entered 'No (N)'	System	02 Nov 2020 11:45:00

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-11-02T03:44:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '15766665-e07a-4e27-801b-948695b7ea50'	System	02 Nov 2020 11:45:00
User entered 'No (N)'	System	02 Nov 2020 11:45:00

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-11-02T03:44:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '15766665-e07a-4e27-801b-948695b7ea50'	System	02 Nov 2020 11:45:00
User entered '02 Nov 2020 03:44:56'	System	02 Nov 2020 11:45:00

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:31:21
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32
Data entry locked.	System	19 Aug 2020 21:54:26
User entered 'Day 92'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 21:54:26

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:46:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:21:32
Data entry locked.	System	19 Aug 2020 21:54:26
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 21:54:26

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-23T14:53:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a9230cc-5cbe-44a0-b6dc-eb4092210f65'	System	23 Nov 2020 22:53:50
User entered 'No (N)'	System	23 Nov 2020 22:53:50

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-23T14:53:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a9230cc-5cbe-44a0-b6dc-eb4092210f65' User entered 'No (N)'	System	23 Nov 2020 22:53:50
	System	23 Nov 2020 22:53:50

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-23T14:53:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a9230cc-5cbe-44a0-b6dc-eb4092210f65' User entered '23 Nov 2020 14:53:45'	System	23 Nov 2020 22:53:50
	System	23 Nov 2020 22:53:50

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-27T13:18:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0af9619e-11a8-4eaf-9056-ed3966053023' User entered 'Yes (Y)'	System	27 Nov 2020 21:18:45
	System	27 Nov 2020 21:18:45

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-27T13:17:49', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0af9619e-11a8-4eaf-9056-ed3966053023' User entered 'No (N)'	System	27 Nov 2020 21:18:45

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-27T13:18:08', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0af9619e-11a8-4eaf-9056-ed3966053023' User entered 'No (N)'	System	27 Nov 2020 21:18:45
	System	27 Nov 2020 21:18:45

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-27T13:18:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0af9619e-11a8-4eaf-9056-ed3966053023' User entered 'No (N)'	System	27 Nov 2020 21:18:45
	System	27 Nov 2020 21:18:45

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-27T13:18:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0af9619e-11a8-4eaf-9056-ed3966053023' User entered '27 Nov 2020 13:18:43'	System	27 Nov 2020 21:18:45
	System	27 Nov 2020 21:18:45

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-04T03:51:52', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '51c7691f-e224-4177-8111-7b13aef48b26' User entered 'Yes (Y)'	System	04 Dec 2020 11:52:28
	System	04 Dec 2020 11:52:28

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-04T03:51:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '51c7691f-e224-4177-8111-7b13aef48b26'	System	04 Dec 2020 11:52:28
User entered 'No (N)'	System	04 Dec 2020 11:52:28

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-04T03:52:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '51c7691f-e224-4177-8111-7b13aef48b26' User entered 'No (N)'	System	04 Dec 2020 11:52:28
	System	04 Dec 2020 11:52:28

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-04T03:52:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '51c7691f-e224-4177-8111-7b13aef48b26' User entered 'No (N)'	System	04 Dec 2020 11:52:28
	System	04 Dec 2020 11:52:28

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-04T03:52:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '51c7691f-e224-4177-8111-7b13aef48b26' User entered '04 Dec 2020 03:52:24'	System	04 Dec 2020 11:52:28
	System	04 Dec 2020 11:52:28

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-11T03:37:08', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '41f5853c-370b-444f-9774-cb981410e3d1' User entered 'Yes (Y)'	System	11 Dec 2020 11:38:29
	System	11 Dec 2020 11:38:29

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-11T03:37:14', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '41f5853c-370b-444f-9774-cb981410e3d1' User entered 'Yes (Y)'	System	11 Dec 2020 11:38:29
	System	11 Dec 2020 11:38:29

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Please 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-11T03:37:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '41f5853c-370b-444f-9774-cb981410e3d1'	System	11 Dec 2020 11:38:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 11:38:29

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-11T03:37:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '41f5853c-370b-444f-9774-cb981410e3d1' User entered 'No (N)'	System	11 Dec 2020 11:38:29
	System	11 Dec 2020 11:38:29

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-11T03:38:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '41f5853c-370b-444f-9774-cb981410e3d1' User entered 'Yes (Y)'	System	11 Dec 2020 11:38:29
	System	11 Dec 2020 11:38:29

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Please 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-11T03:38:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '41f5853c-370b-444f-9774-cb981410e3d1'	System	11 Dec 2020 11:38:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 11:38:29

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-11T03:38:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '41f5853c-370b-444f-9774-cb981410e3d1' User entered '11 Dec 2020 03:38:18'	System	11 Dec 2020 11:38:29
	System	11 Dec 2020 11:38:29

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-18T03:43:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '93e82ffd-ffbf-416e-8c66-51bef5424134' User entered 'No (N)'	System	18 Dec 2020 11:43:43
	System	18 Dec 2020 11:43:43

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-18T03:43:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '93e82ffd-ffbf-416e-8c66-51bef5424134' User entered 'No (N)'	System	18 Dec 2020 11:43:43
	System	18 Dec 2020 11:43:43

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-18T03:43:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '93e82ffd-ffbf-416e-8c66-51bef5424134' User entered '18 Dec 2020 03:43:37'	System	18 Dec 2020 11:43:43
	System	18 Dec 2020 11:43:43

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-25T07:18:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7890f080-4642-4486-8eac-07e95ae0086d' User entered 'No (N)'	System	25 Dec 2020 15:18:31
	System	25 Dec 2020 15:18:31

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-25T07:18:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7890f080-4642-4486-8eac-07e95ae0086d' User entered 'No (N)'	System	25 Dec 2020 15:18:31

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-12-25T07:18:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7890f080-4642-4486-8eac-07e95ae0086d' User entered '25 Dec 2020 07:18:26'	System	25 Dec 2020 15:18:31
	System	25 Dec 2020 15:18:31

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-04T18:01:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0a2929-4fba-470e-be13-612bb0e5ad11'	System	05 Jan 2021 02:01:38
User entered 'No (N)'	System	05 Jan 2021 02:01:38

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-04T18:01:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0a2929-4fba-470e-be13-612bb0e5ad11'	System	05 Jan 2021 02:01:38
User entered 'No (N)'	System	05 Jan 2021 02:01:38

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-04T18:01:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0a2929-4fba-470e-be13-612bb0e5ad11' User entered '04 Jan 2021 18:01:29'	System	05 Jan 2021 02:01:38
	System	05 Jan 2021 02:01:38

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-10T12:48:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9883bcf7-cbd1-4cd2-9130-4b887459ad44'	System	10 Jan 2021 20:49:26
User entered 'No (N)'	System	10 Jan 2021 20:49:26

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-10T12:49:01', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9883bcf7-cbd1-4cd2-9130-4b887459ad44'	System	10 Jan 2021 20:49:26
User entered 'No (N)'	System	10 Jan 2021 20:49:26

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-10T12:49:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9883bcf7-cbd1-4cd2-9130-4b887459ad44' User entered '10 Jan 2021 12:49:21'	System	10 Jan 2021 20:49:26
	System	10 Jan 2021 20:49:26

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-17T12:01:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1f9ab4b2-1bb5-4509-affd-a14bc13a382f' User entered 'No (N)'	System	17 Jan 2021 20:01:41
	System	17 Jan 2021 20:01:41

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-17T12:01:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1f9ab4b2-1bb5-4509-affd-a14bc13a382f' User entered 'No (N)'	System	17 Jan 2021 20:01:41
	System	17 Jan 2021 20:01:41

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-17T12:01:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1f9ab4b2-1bb5-4509-affd-a14bc13a382f' User entered '17 Jan 2021 12:01:33'	System	17 Jan 2021 20:01:41
	System	17 Jan 2021 20:01:41

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-22T05:23:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bed2af65-3761-4c14-8a86-4f9a96e58df9' User entered 'No (N)'	System	22 Jan 2021 13:24:01
	System	22 Jan 2021 13:24:01

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-22T05:23:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bed2af65-3761-4c14-8a86-4f9a96e58df9' User entered 'No (N)'	System	22 Jan 2021 13:24:01

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-22T05:23:57', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bed2af65-3761-4c14-8a86-4f9a96e58df9' User entered '22 Jan 2021 05:23:57'	System	22 Jan 2021 13:24:01
	System	22 Jan 2021 13:24:01

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-31T13:00:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bbc077af-b56b-483e-85d3-3be4af02dd29' User entered 'No (N)'	System	31 Jan 2021 21:00:41
	System	31 Jan 2021 21:00:41

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-31T13:00:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bbc077af-b56b-483e-85d3-3be4af02dd29' User entered 'No (N)'	System	31 Jan 2021 21:00:41

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-01-31T13:00:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bbc077af-b56b-483e-85d3-3be4af02dd29' User entered '31 Jan 2021 13:00:37'	System	31 Jan 2021 21:00:41
	System	31 Jan 2021 21:00:41

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-05T03:27:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'df251b01-7bce-4975-9ddc-b88dda220ff4'	System	05 Feb 2021 11:27:46
User entered 'No (N)'	System	05 Feb 2021 11:27:46

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-05T03:27:38', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'df251b01-7bce-4975-9ddc-b88dda220ff4' User entered 'No (N)'	System	05 Feb 2021 11:27:46
	System	05 Feb 2021 11:27:46

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-05T03:27:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'df251b01-7bce-4975-9ddc-b88dda220ff4' User entered '05 Feb 2021 03:27:41'	System	05 Feb 2021 11:27:46
	System	05 Feb 2021 11:27:46

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-14T12:42:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'e55d3093-b7b1-43ed-8641-474897dc61e8' User entered 'No (N)'	System	14 Feb 2021 20:43:09

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-14T12:43:01', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'e55d3093-b7b1-43ed-8641-474897dc61e8' User entered 'No (N)'	System	14 Feb 2021 20:43:09

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-14T12:43:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'e55d3093-b7b1-43ed-8641-474897dc61e8' User entered '14 Feb 2021 12:43:06'	System	14 Feb 2021 20:43:09
	System	14 Feb 2021 20:43:09

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-21T08:55:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '30fb8203-c1d4-4d5e-88bc-ccecf614371c' User entered 'No (N)'	System	21 Feb 2021 16:55:37
	System	21 Feb 2021 16:55:37

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-21T08:55:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '30fb8203-c1d4-4d5e-88bc-ccecf614371c'	System	21 Feb 2021 16:55:37
User entered 'No (N)'	System	21 Feb 2021 16:55:37

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-21T08:55:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '30fb8203-c1d4-4d5e-88bc-ccecf614371c' User entered '21 Feb 2021 08:55:33'	System	21 Feb 2021 16:55:37
	System	21 Feb 2021 16:55:37

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-27T07:53:31-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bc88faf6-270b-4853-9e71-8212d6401e5a'	System	27 Feb 2021 15:53:42
User entered 'No (N)'	System	27 Feb 2021 15:53:42

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-27T07:53:35-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bc88faf6-270b-4853-9e71-8212d6401e5a'	System	27 Feb 2021 15:53:42
User entered 'No (N)'	System	27 Feb 2021 15:53:42

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-27T07:53:39-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'bc88faf6-270b-4853-9e71-8212d6401e5a' User entered '27 Feb 2021 15:53:39'	System	27 Feb 2021 15:53:42
	System	27 Feb 2021 15:53:42

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-05T13:22:47-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f1c4773c-b62a-45a2-ace5-76fa73e7c385'	System	05 Mar 2021 21:23:08
User entered 'No (N)'	System	05 Mar 2021 21:23:08

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-05T13:22:54-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f1c4773c-b62a-45a2-ace5-76fa73e7c385'	System	05 Mar 2021 21:23:08
User entered 'No (N)'	System	05 Mar 2021 21:23:08

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-05T13:23:00-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f1c4773c-b62a-45a2-ace5-76fa73e7c385'	System	05 Mar 2021 21:23:08
User entered '05 Mar 2021 13:23:00'	System	05 Mar 2021 21:23:08

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-12T00:21:58-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '8cef7bb4-7cd1-41c4-9277-8d95a7a1dba5'	System	12 Mar 2021 08:22:19
User entered 'No (N)'	System	12 Mar 2021 08:22:19

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-12T00:22:12-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '8cef7bb4-7cd1-41c4-9277-8d95a7a1dba5'	System	12 Mar 2021 08:22:19
User entered 'No (N)'	System	12 Mar 2021 08:22:19

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-12T00:22:16-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '8cef7bb4-7cd1-41c4-9277-8d95a7a1dba5'	System	12 Mar 2021 08:22:19
User entered '12 Mar 2021 00:22:16'	System	12 Mar 2021 08:22:19

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-19T03:54:00-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3efd8768-0f63-4124-bb1e-bceabc120235'	System	26 Mar 2021 18:35:22
User entered 'No (N)'	System	26 Mar 2021 18:35:22

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-19T03:54:10-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3efd8768-0f63-4124-bb1e-bceabc120235'	System	26 Mar 2021 18:35:22
User entered 'No (N)'	System	26 Mar 2021 18:35:22

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-19T03:54:15-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3efd8768-0f63-4124-bb1e-bceabc120235'	System	26 Mar 2021 18:35:22
User entered '19 Mar 2021 03:54:15'	System	26 Mar 2021 18:35:22

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-26T11:35:23-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '971abdc6-4ad3-4f92-ac0c-cff31518b018'	System	26 Mar 2021 18:35:34
User entered 'No (N)'	System	26 Mar 2021 18:35:34

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-26T11:35:26-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '971abdc6-4ad3-4f92-ac0c-cff31518b018'	System	26 Mar 2021 18:35:34
User entered 'No (N)'	System	26 Mar 2021 18:35:34

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-03-26T11:35:31-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '971abdc6-4ad3-4f92-ac0c-cff31518b018' User entered '26 Mar 2021 11:35:31'	System	26 Mar 2021 18:35:34
	System	26 Mar 2021 18:35:34

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-02T05:23:19-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'c8cff6bf-ce9b-47a9-9239-f6256f7e2504'	System	02 Apr 2021 12:23:36
User entered 'No (N)'	System	02 Apr 2021 12:23:36

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-02T05:23:24-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'c8cff6bf-ce9b-47a9-9239-f6256f7e2504'	System	02 Apr 2021 12:23:36
User entered 'No (N)'	System	02 Apr 2021 12:23:36

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-02T05:23:31-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'c8cff6bf-ce9b-47a9-9239-f6256f7e2504'	System	02 Apr 2021 12:23:36
User entered '02 Apr 2021 05:23:31'	System	02 Apr 2021 12:23:36

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-11T14:08:43-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25153ac4-e92f-43ce-8250-94fa880a0abd' User entered 'No (N)'	System	11 Apr 2021 21:08:57
	System	11 Apr 2021 21:08:57

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-11T14:08:50-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25153ac4-e92f-43ce-8250-94fa880a0abd' User entered 'No (N)'	System	11 Apr 2021 21:08:57
	System	11 Apr 2021 21:08:57

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-11T14:08:54-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25153ac4-e92f-43ce-8250-94fa880a0abd' User entered '11 Apr 2021 14:08:54'	System	11 Apr 2021 21:08:57
	System	11 Apr 2021 21:08:57

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-16T06:54:22-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '732abdd8-08c8-4baf-a3f6-2a7ab5265bfa' User entered 'No (N)'	System	16 Apr 2021 13:54:44
	System	16 Apr 2021 13:54:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-16T06:54:31-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '732abdd8-08c8-4baf-a3f6-2a7ab5265bfa' User entered 'No (N)'	System	16 Apr 2021 13:54:44
	System	16 Apr 2021 13:54:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-16T06:54:38-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '732abdd8-08c8-4baf-a3f6-2a7ab5265bfa' User entered '16 Apr 2021 06:54:38'	System	16 Apr 2021 13:54:44
	System	16 Apr 2021 13:54:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-23T08:12:52-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '135fffe3-0e93-481b-9154-62ab74fb890d'	System	23 Apr 2021 15:13:23
User entered 'No (N)'	System	23 Apr 2021 15:13:23

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-23T08:12:57-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '135fffe3-0e93-481b-9154-62ab74fb890d'	System	23 Apr 2021 15:13:23
User entered 'No (N)'	System	23 Apr 2021 15:13:23

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-23T08:13:00-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '135ffe3-0e93-481b-9154-62ab74fb890d'	System	23 Apr 2021 15:13:23
User entered '23 Apr 2021 08:13:00'	System	23 Apr 2021 15:13:23

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-30T04:18:21-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a636252-f2b0-4ad7-b13e-008003607e64'	System	30 Apr 2021 11:19:44
User entered 'Yes (Y)'	System	30 Apr 2021 11:19:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-30T04:18:35-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a636252-f2b0-4ad7-b13e-008003607e64'	System	30 Apr 2021 11:19:44
User entered 'No (N)'	System	30 Apr 2021 11:19:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-30T04:18:44-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a636252-f2b0-4ad7-b13e-008003607e64'	System	30 Apr 2021 11:19:44
User entered 'No (N)'	System	30 Apr 2021 11:19:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-30T04:19:00-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a636252-f2b0-4ad7-b13e-008003607e64'	System	30 Apr 2021 11:19:44
User entered 'Yes (Y)'	System	30 Apr 2021 11:19:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Please 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-30T04:19:14-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a636252-f2b0-4ad7-b13e-008003607e64'	System	30 Apr 2021 11:19:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Apr 2021 11:19:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-04-30T04:19:29-07:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a636252-f2b0-4ad7-b13e-008003607e64'	System	30 Apr 2021 11:19:44
User entered '30 Apr 2021 04:19:29'	System	30 Apr 2021 11:19:44

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:21:32

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:21:32
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:21:32

US3462255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:38:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'Updated ConMeds' (Site from DM).	(b) (4), (b) (6)	03 May 2021 17:26:17
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).		24 Mar 2021 01:42:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-27T07:53:58-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a4fb04d-1933-4c52-9cea-797a321742fe'	System	27 Feb 2021 15:54:21
User entered 'Yes (Y)'	System	27 Feb 2021 15:54:21

US3462255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:38:14

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-27T07:54:06-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a4fb04d-1933-4c52-9cea-797a321742fe' User entered 'Yes (Y)'	System	27 Feb 2021 15:54:21
	System	27 Feb 2021 15:54:21

US3462255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:38:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2021-02-27T07:54:13-08:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a4fb04d-1933-4c52-9cea-797a321742fe'	System	27 Feb 2021 15:54:21
User entered '27 Feb 2021 15:54:13'	System	27 Feb 2021 15:54:21

US3462255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	17 Nov 2020 19:15:53

US3462255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
User entered '13 Nov 2020'	(b) (4) Danuel Hamlin (b) (4)	17 Nov 2020 19:15:53

US3462255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	17 Nov 2020 19:15:53

US3462255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	17 Nov 2020 19:15:53

US3462255

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	17 Nov 2020 19:16:52

US3462255

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:45:52
User entered 'I'	System	17 Nov 2020 19:16:52

US3462255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:15:53
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Apr 2021 20:15:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:47

US3462255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:15:53
User entered '7 Dec 2020' reason for change: Data Entry Error		05 Apr 2021 20:15:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:47

US3462255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:15:53
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 20:15:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:47

US3462255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:47

US3462255

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:50

US3462255

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'I'	System	11 Mar 2021 17:30:50

US3462255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:14:34
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Apr 2021 20:14:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:56

US3462255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:14:34
User entered '11 Jan 2021' reason for change: Data Entry Error		05 Apr 2021 20:14:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:56

US3462255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:14:34
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error		05 Apr 2021 20:14:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:56

US3462255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:56

US3462255

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:00

US3462255

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'I'	System	11 Mar 2021 17:31:00

US3462255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 20:14:58
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Apr 2021 20:14:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:31:06

US3462255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:14:58
User entered '15 Feb 2021' reason for change: Data Entry Error		05 Apr 2021 20:14:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:06

US3462255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:27:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:14:58
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error		05 Apr 2021 20:14:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:06

US3462255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:06

US3462255

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:09

US3462255

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'I'	System	11 Mar 2021 17:31:09

US3462255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User closed query 'Per CDM: Vital Signs page has not been entered, please complete.' (Site from DM).		02 Apr 2021 12:42:32
Query 'Per CDM: Vital Signs page has not been entered, please complete.' answered with 'updated' (Site from DM).		01 Apr 2021 19:38:48
User opened query 'Per CDM: Vital Signs page has not been entered, please complete.' (Site from DM).		30 Mar 2021 12:37:45
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:27

US3462255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:27

US3462255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:27

US3462255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'VISIT4'	System	11 Mar 2021 17:31:27

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User closed query 'Per CDM: Thank you for recording the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 04MAR2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review, reconcile and update as appropriate. ' (Site from DM).		14 Apr 2021 10:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Query 'Per CDM: Thank you for recording the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 04MAR2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review, reconcile and update as appropriate. ' answered with 'updated data' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:36
Signature has been broken.		12 Apr 2021 23:16:28
User entered 'Yes (Y)' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User opened query 'Per CDM: Thank you for recording the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 04MAR2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review, reconcile and update as appropriate. ' (Site from DM).		02 Apr 2021 12:42:56
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered '04 Mar 2021' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered '13:18' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered '04 Mar 2021 13:18'	System	12 Apr 2021 23:16:28
User entered empty.	System	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered '98' F reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered 'Oral (Oral)' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered '75' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'bpm'	System	12 Apr 2021 23:16:28
User entered empty.	System	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered '13' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'breaths/min'	System	12 Apr 2021 23:16:28
User entered empty.	System	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered '123' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'mmHg'	System	12 Apr 2021 23:16:28
User entered empty.	System	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:45:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:16:28
User entered '81' reason for change: Data Entry Error		12 Apr 2021 23:16:28
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'mmHg'	System	12 Apr 2021 23:16:28
User entered empty.	System	01 Apr 2021 18:55:07

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08

US3462255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08

US3462255

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:31

US3462255

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:31

US3462255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:41

US3462255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:41

US3462255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '13:40'	(b) (4) (o) (4), (b) (6)	11 Mar 2021 17:31:41

US3462255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered '04 Mar 2021 13:40'	System	11 Mar 2021 17:31:41

US3462255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:31:46

US3462255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:33:08
User entered 'I'	System	11 Mar 2021 17:31:46

US3462255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:14:32

US3462255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:14:32

US3462255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:14:32

US3462255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 17:14:32

US3462255

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

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:26

US3462255

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

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:26

US3462255

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

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:26

US3462255

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

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 21:40:26

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:53:16

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:53:16

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '1'	System	22 Feb 2021 21:40:56

US3462255

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

Form: Unblinding

Generated On: 09 Jun 2021 17:38:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'I'	System	22 Feb 2021 21:40:56

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '165' cm	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '83.5' kg	(b) (4) (o) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '30.67034'	System	22 Feb 2021 21:43:25
DataPoint set to visible.	System	22 Feb 2021 21:40:56

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '165' cm	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '83.5' kg	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '30.67034'	System	22 Feb 2021 21:43:25
DataPoint set to visible.	System	22 Feb 2021 21:40:56

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User accepted default value 'Pre-Dose (PREDOSE)'		22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '11:50'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '05 Feb 2021 11:50'	System	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '72'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'bpm'	System	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'breaths/min'	System	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '130'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '80'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '165' cm	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '83.5' kg	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:43:25

US3462255

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '30.67034'	System	22 Feb 2021 21:43:25
DataPoint set to visible.	System	22 Feb 2021 21:40:56

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User accepted default value 'Post-Dose (POSTDOSE)'		22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '12:40'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '05 Feb 2021 12:40'	System	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '90'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'bpm'	System	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '14'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'breaths/min'	System	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '138'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '90'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:02

US3462255

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	22 Feb 2021 21:44:02

US3462255

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:14

US3462255

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:14

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mRNA-1273'	System	22 Feb 2021 21:44:32
DataPoint set to visible.	System	22 Feb 2021 21:40:56

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '12:10'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '05 Feb 2021 12:10'	System	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'ONCE'	System	22 Feb 2021 21:44:32

US3462255

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

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 21:44:32

US3462255

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Mar 2021 19:43:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:41:08

US3462255

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 05Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User signature succeeded.	(b) (4)	31 Mar 2021 15:21:48
	Gregg Lucksinger (b) (4)	26 Mar 2021 19:43:51
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 05Feb2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'Confirmed Sample was shipped, however due to extreme weather samples were received at PPD beyond stability. Extreme weather caused delays in delivery of shipments from courier.' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 05Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '05 Feb 2021'	(b) (4), (b) (6)	26 Mar 2021 16:29:11
		24 Feb 2021 19:11:35
		22 Feb 2021 21:41:08

US3462255

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Mar 2021 19:43:51
User entered '11:30'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:41:08

US3462255

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '05 Feb 2021 11:30'	System	22 Feb 2021 21:41:08

US3462255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:41:17

US3462255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:38:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:41:17

US3462255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '11:20'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:41:17

US3462255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:38:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '05 Feb 2021 11:20'	System	22 Feb 2021 21:41:17

US3462255

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

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:41:20

US3462255

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

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'I'	System	22 Feb 2021 21:41:20

US3462255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:00

US3462255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:00

US3462255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:00

US3462255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:00

US3462255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:04

US3462255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'I'	System	11 Mar 2021 17:28:04

US3462255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'I'	System	11 Mar 2021 17:28:04
DataPoint set to visible.	System	11 Mar 2021 17:28:04

US3462255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (o) (4), (b) (6)	11 Mar 2021 17:28:30

US3462255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:30

US3462255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:28:30

US3462255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'OLD29'	System	11 Mar 2021 17:28:30

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User accepted default value 'Pre-Dose (PREDOSE)'		11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '13:18'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '04 Mar 2021 13:18'	System	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '75'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'bpm'	System	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '13'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'breaths/min'	System	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '123'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '81'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	11 Mar 2021 17:29:00

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User accepted default value 'Post-Dose (POSTDOSE)'		11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '14:18'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '04 Mar 2021 14:18'	System	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '76'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'bpm'	System	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'breaths/min'	System	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '141'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '88'	(b) (4) (u) (4), (b) (6)	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mmHg'	System	11 Mar 2021 17:29:45

US3462255

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:03

US3462255

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:03

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'mRNA-1273'	System	11 Mar 2021 17:30:21
DataPoint set to visible.	System	11 Mar 2021 17:28:04

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '13:45'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered '04 Mar 2021 13:45'	System	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'ONCE'	System	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'INTRAMUSCULAR'	System	11 Mar 2021 17:30:21

US3462255

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:30:24

US3462255

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'I'	System	11 Mar 2021 17:30:24

US3462255

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 16:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:25:16

US3462255

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 16:14:58
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	05 Apr 2021 15:25:29
User entered '11 Mar 2021' reason for change: Data Entry Error	System	05 Apr 2021 15:25:29
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:25:16
User entered '10 Mar 2021'	System	05 Apr 2021 15:25:16

US3462255

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 16:14:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:25:16

US3462255

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:38:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 16:14:58
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:25:16

US3462255

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 16:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:25:36

US3462255

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:38:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:54:05
User entered 'I'	System	05 Apr 2021 15:25:36

US3462255

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:18

US3462255

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:18

US3462255

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:18

US3462255

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 18:14:18

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:14:26

US3462255

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:34

US3462255

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:34

US3462255

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:43

US3462255

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:43

US3462255

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:43
User entered '12:45'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:14:43

US3462255

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 12:45'	System	05 Apr 2021 18:14:43

US3462255

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:38:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:05:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:44:31
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:11:38

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:25:53
Reviewed for Safety.		21 Oct 2020 21:06:06
User entered 'USA-US093-2020-mRNA-1273-P301000008'	System	21 Oct 2020 21:06:01
User entered 'New'	(b) (4), (b) (6)	21 Oct 2020 21:06:01

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:37:16
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 00:22:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 00:22:28
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 00:21:11
User entered 'Dehydration'	Daniel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4)	17 Nov 2020 22:37:26
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 22:37:21
DataPoint Verified.		17 Nov 2020 22:37:19
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:23
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:28
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Un-verified.	(b) (4)	03 May 2021 16:58:47
	(b) (4), (b) (6)	03 May 2021 16:58:47
User entered '9 Oct 2020' reason for change: Data Entry Error		03 May 2021 16:58:47
User closed query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms' (Site from Safety).		30 Apr 2021 13:11:31
Query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms' answered with 'The symptoms started on 16OCT2021, the same date as the onset of the anemia.' (Site from Safety).		29 Apr 2021 20:20:36
User opened query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms' (Site from Safety).		29 Apr 2021 19:09:57
DataPoint Verified.		17 Nov 2020 22:37:31
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).		07 Nov 2020 00:14:06

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' answered with 'Subject had mild symptoms of fatigue and general weakness 1 week prior to hospitalization, however, no diagnosis of dehydration or anemia until date of hospitalization. (Site from Safety).	Danuel Hamlin (b) (4)	06 Nov 2020 00:13:12
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 22:58:23
User entered '16 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:37
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		12 Nov 2020 15:06:21
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed. Start date/time is correct.' (Site from System).	Danuel Hamlin (b) (4)	21 Oct 2020 00:21:40
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Oct 2020 00:20:55
User entered '08:00'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020 08:00'	System	03 May 2021 16:58:47
Query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:09:49
User opened query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms.' (Site from Safety).		13 Nov 2020 20:53:14
User entered '16 Oct 2020 08:00'	System	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:40
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:42
User entered '17 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:37:45
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).		13 Nov 2020 15:37:43
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Confirmed. Time is correct' (Site from System).	Danuel Hamlin (b) (4)	21 Oct 2020 00:21:50
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Oct 2020 00:20:55
User entered '12:00'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:49
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:54
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:56
User entered '0'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:01
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:37:59
User entered 'I'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:03
User entered '16 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:05
User entered '17 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:07
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:39
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:42
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:44
User entered '0'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:50
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:52
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:55
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:38:58
User entered 'Not Applicable (NOT APPLICABLE)'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:39:03
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:39:05
User entered 'I'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:39:07
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:39:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:39:11
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User closed query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 17:47:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		03 May 2021 17:47:00
Query 'PV Query: Please provide the etiology of the dehydration and anemia.' answered with 'We have no been sent medical records after having requested them. We cannot currently answer query.' (Site from Safety).		03 May 2021 15:19:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'We have not been sent medical records after having requested them. We cannot currently answer query.' (Site from Safety).		03 May 2021 15:18:13
Query 'Per DM CLR: Narrative indicates that the subject was treated with Fluids for Dehydration. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'We have not been sent medical records after having requested them. We cannot currently answer query.' (Site from DM).		03 May 2021 15:17:39
User opened query 'Per DM CLR: Narrative indicates that the subject was treated with Fluids for Dehydration. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		29 Nov 2020 12:10:37
DataPoint Verified.		17 Nov 2020 22:39:16
User opened query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).		13 Nov 2020 20:52:54

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 20:52:38
User closed query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).		07 Nov 2020 00:13:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		07 Nov 2020 00:12:55
Query 'PV Query: Please provide the etiology of the dehydration and anemia.' answered with 'Pending receipt of outside medical records. ' (Site from Safety).	Danuel Hamlin (b) (4)	06 Nov 2020 00:13:54
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pending receipt of outside medical records from hospital.' (Site from Safety).	Danuel Hamlin (b) (4)	06 Nov 2020 00:13:44
User opened query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 22:58:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		30 Oct 2020 22:58:02
User entered '57 year old female with hypertension, type II diabetes, GERD, and history of gastric bypass surgery on 02OCT2020. Subject woke up 16OCT2020 with increased fatigue and malaise. Those symptoms had been ongoing for approximately one week prior, but suddenly worsened. Subject went to Emergency Department morning of 16OCT2020 at approximately 09:30 and was diagnosed with severe dehydration and anemia. Subject was treated with IV fluids and iron supplementation. Subject was admitted to monitor kidney function. Symptoms improved with treatments. Subject was discharged 17OCT2020 at approximately 12:00 with instructions to take over the counter iron supplementation.'	Danuel Hamlin (b) (4)	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 00:20:55

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
Reviewed for Safety.		21 Oct 2020 21:12:58
User entered 'USA-US093-2020-mRNA-1273-P301000008'		21 Oct 2020 21:06:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:41:12
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 00:25:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 00:25:30
Data point term sent to Coder	System	21 Oct 2020 00:24:16
User entered 'Anemia'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User closed query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 May 2021 17:47:59
Query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms.' answered with 'Updated' (Site from Safety).		03 May 2021 16:57:56
DataPoint Un-verified.		03 May 2021 16:57:46
User entered '9 Oct 2020' reason for change: Data Entry Error		03 May 2021 16:57:46
DataPoint Verified.		17 Nov 2020 22:41:12
User opened query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms.' (Site from Safety).		13 Nov 2020 20:53:37
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).		07 Nov 2020 00:10:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' answered with 'Subject had mild symptoms of fatigue and general weakness 1 week prior to hospitalization, however, no diagnosis of dehydration or anemia until date of hospitalization. We will review outside medical records once received and PI can determine if start date should be changed. ' (Site from Safety).	Danuel Hamlin (b) (4)	06 Nov 2020 00:15:57
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 22:59:15
User entered '16 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User closed query 'Start time is present for an AE tha did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		12 Nov 2020 15:06:07
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed. Time is correct' (Site from System).	Danuel Hamlin (b) (4)	21 Oct 2020 00:24:57
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Oct 2020 00:23:29
User entered '08:00'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020 08:00'	System	03 May 2021 16:57:46
User entered '16 Oct 2020 08:00'	System	21 Oct 2020 00:23:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 20:17:22
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 20:16:20
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 20:16:20
User entered 'Yes (Y)' reason for change: Data Entry Error		29 Apr 2021 20:16:20
DataPoint Verified.		17 Nov 2020 22:41:12
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	29 Apr 2021 20:18:28
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	29 Apr 2021 20:18:28
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 20:17:22
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 20:17:22
User entered empty; reason for change Data Entry Error		29 Apr 2021 20:17:22
DataPoint Verified.		17 Nov 2020 22:41:12
User entered '17 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
	(b) (4)	
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	29 Apr 2021 20:17:22
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 20:17:22
User entered empty; reason for change Data Entry Error		29 Apr 2021 20:17:22
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	29 Apr 2021 20:16:20
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	29 Apr 2021 20:16:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:41:12
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).		12 Nov 2020 15:06:05
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Confirmed. ' (Site from System).	Danuel Hamlin (b) (4)	21 Oct 2020 00:25:03
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Oct 2020 00:23:29
User entered '12:00'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:17:22
User entered '17 Oct 2020 12:00'	System	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'I'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '16 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '17 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'Not Applicable (NOT APPLICABLE)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered 'I'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered '0'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:18:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error		29 Apr 2021 20:18:28
DataPoint Verified.		17 Nov 2020 22:41:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:12
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User closed query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 May 2021 17:48:12
Query 'PV Query: Please provide the etiology of the dehydration and anemia.' answered with 'We have not yet received patient's medical records and so are unable to answer this query.' (Site from Safety).		03 May 2021 16:58:28
DataPoint Verified.		17 Nov 2020 22:41:12
User opened query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).		13 Nov 2020 20:53:50
User closed query 'PV Query: Please report if the subject had any prior history of anemia, or risk factors for developing anemia.' (Site from Safety).		07 Nov 2020 00:11:35
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		07 Nov 2020 00:11:13
Query 'PV Query: Please report if the subject had any prior history of anemia, or risk factors for developing anemia.' answered with 'No history of anemia reported.' (Site from Safety).	Danuel Hamlin (b) (4)	06 Nov 2020 00:29:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pending receipt of outside medical records.' (Site from Safety).	Danuel Hamlin (b) (4)	06 Nov 2020 00:28:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 22:59:27
User opened query 'PV Query: Please report if the subject had any prior history of anemia, or risk factors for developing anemia.' (Site from Safety).		30 Oct 2020 22:58:59

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Narrative](#)

Audit	User	Time (GMT)
User entered '57 year old female with hypertension, type II diabetes, GERD, and history of gastric bypass surgery on 02OCT2020. Subject woke up 16OCT2020 with increased fatigue and malaise. Those symptoms had been ongoing for approximately one week prior, but suddenly worsened. Subject went to Emergency Department morning of 16OCT2020 at approximately 09:30 and was diagnosed with severe dehydration and anemia. Subject was treated with IV fluids and iron supplementation. Subject was admitted to monitor kidney function. Symptoms improved with treatments. Subject was discharged 17OCT2020 at approximately 12:00 with instructions to take over the counter iron supplementation.'	Danuel Hamlin (b) (4)	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 00:23:29

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:38:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 00:23:29

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:38:14

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' answered with 'Patient is not aware what dermal filler she received.' (Site from DM).	(b) (4), (b) (6)	03 May 2021 17:22:03
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).		19 Mar 2021 17:36:11
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:41:39
User entered 'Yes (Y)'		20 Aug 2020 19:13:53

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:52:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:17:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:17:28
Data point term sent to Coder	System	20 Aug 2020 19:16:08
User entered 'hydrochlorathiazide'	(b) (4), (b) (6)	20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered 'No (N)'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered 'hypertension'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered '12.5'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered 'mg (mg)'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered empty.		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered 'once daily (QD)'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered empty.		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered 'Oral (ORAL)'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered empty.		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:15:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:15:19
User entered 'un UNK 2000'	(b) (4), (b) (6)	20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered '0'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered 'Yes (Y)'		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User entered empty.		20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:02
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 19:15:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 19:15:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 19:15:39
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 19:15:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:15:19

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:52:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:18:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:18:18
Data point term sent to Coder	System	20 Aug 2020 19:17:10
User entered 'meloxicam'	(b) (4), (b) (6)	20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered 'No (N)'		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered 'osteoarthritis'		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User closed query 'Per CDM, per eCRF completion guidelines unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:15:28
		17 Nov 2020 22:52:44
User entered '15' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:18:17
Query 'Per CDM, per eCRF completion guidelines unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 00:17:43
User entered 'UNK' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:17:37
User opened query 'Per CDM, per eCRF completion guidelines unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM). User entered 'unknown'	(b) (4), (b) (6)	09 Sep 2020 09:29:01
		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered 'mg (mg)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:18:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:18:17
User entered 'unknown'	(b) (4), (b) (6)	20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered 'as needed (PRN)'		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered empty.		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered 'Oral (ORAL)'		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered empty.		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:39:02
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:16:40
User entered 'un UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered '0'		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered 'Yes (Y)'		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered empty.		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:52:44
User entered 'No (N)'		20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:16:40

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 00:20:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 00:20:24
	(b) (4)	
Data point term sent to Coder	System	06 Nov 2020 00:19:40
Coding entries removed.	Danuel Hamlin (b) (4)	06 Nov 2020 00:19:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 19:20:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 19:20:24
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 19:19:19
User entered 'metformin'	(b) (4), (b) (6)	20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Type II Diabetes' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:19:13
User entered 'DMT2'	(b) (4), (b) (6)	20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '1000' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:38:01
DataPoint Un-verified.		22 Feb 2021 21:37:42
User entered '500' reason for change: Data Entry Error		22 Feb 2021 21:37:42
User closed query 'Per DM CLR: Please consider recording these two dose separately instead of recording the both in the same entry. Update as appropriate.' (Site from DM).		18 Nov 2020 11:16:29
DataPoint Verified.		17 Nov 2020 23:00:31
User entered '2500' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:20:33
Query 'Per DM CLR: Please consider recording these two dose separately instead of recording the both in the same entry. Update as appropriate.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 00:19:10
User entered '1000' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:18:57
User opened query 'Per DM CLR: Please consider recording these two dose separately instead of recording the both in the same entry. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:24:41
User entered '1000 mg q am; 1500 mg qpm'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per source, subject is taking Metformin twice daily (1000mg in the AM starting in 2017 and 1500mg in the PM starting in Feb2020). Please split these into 2 separate ConMed entries. ' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	21 Apr 2021 19:51:02
Query 'Per source, subject is taking Metformin twice daily (1000mg in the AM starting in 2017 and 1500mg in the PM starting in Feb2020). Please split these into 2 separate ConMed entries. ' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
	(b) (4), (b) (6)	22 Feb 2021 21:38:10
		22 Feb 2021 21:37:42
User entered 'twice daily (BID)' reason for change: Data Entry Error		22 Feb 2021 21:37:42
DataPoint Verified.		17 Nov 2020 23:00:31
User opened query 'Per source, subject is taking Metformin twice daily (1000mg in the AM starting in 2017 and 1500mg in the PM starting in Feb2020). Please split these into 2 separate ConMed entries. ' (Site from CRA). User entered 'once daily (QD)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:20:33
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:36
User entered 'UN UNK 2017' reason for change: Data Entry Error		22 Feb 2021 21:39:36
DataPoint Verified.		17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:19:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:19:17
User entered 'un Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 19:19:17
User entered '20 Aug 2020'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Feb 2021 21:37:42
User entered '1'	System	06 Nov 2020 00:20:33
User entered '2'	System	20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:18:43

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:13:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:13:32
Data point term sent to Coder Coding entries removed.	System Danuel Hamlin (b) (4)	06 Nov 2020 00:21:43 06 Nov 2020 00:21:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:22:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:22:28
Data point term sent to Coder User entered 'metoprolol'	System (b) (4), (b) (6)	20 Aug 2020 19:21:27 20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User closed query 'Per DM CLR: Please update the indication to reflect the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:17:48
		17 Nov 2020 23:00:31
Query 'Per DM CLR: Please update the indication to reflect the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Type of tachycardia not specified' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 00:21:32
User entered 'Occasional TACHYCARDIA' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:21:28
User opened query 'Per DM CLR: Please update the indication to reflect the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). User entered 'tachycardia'	(b) (4), (b) (6)	21 Oct 2020 07:26:59
		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '25'		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'once daily (QD)'		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:20:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:20:27
User entered 'un UNK 2000'	(b) (4), (b) (6)	20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 19:20:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 19:20:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 19:20:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 19:20:27
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:20:27

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:23:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:23:31
Data point term sent to Coder	System	20 Aug 2020 19:22:28
User entered 'omeprazole'	(b) (4), (b) (6)	20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'GERD'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '40'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'once daily (QD)'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:21:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:21:35
User entered 'un UNK 1995'	(b) (4), (b) (6)	20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:21:35

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
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) (b) (4)	21 Aug 2020 04:03:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 04:03:14
Data point term sent to Coder	System	20 Aug 2020 19:23:32
User entered 'aspirin'	(b) (4), (b) (6)	20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'cardiac risk'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '81'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'once daily (QD)'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:22:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:22:50
User entered 'un UNK 1995'	(b) (4), (b) (6)	20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:22:50

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
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)	20 Aug 2020 19:25:25
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 19:25:25
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	20 Aug 2020 19:24:32
User entered 'atorvastatin'	(b) (4), (b) (6)	20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'hypercholesterolemia'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '10'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'once daily (QD)'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:24:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:24:12
User entered 'un UNK 2010'	(b) (4), (b) (6)	20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:24:12

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:23:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:23:29
Data point term sent to Coder Coding entries removed.	System Danuel Hamlin (b) (4)	06 Nov 2020 00:22:44 06 Nov 2020 00:22:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:26:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:26:26
Data point term sent to Coder User entered 'cyclobenzaprine'	System (b) (4), (b) (6)	20 Aug 2020 19:25:36 20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:18:31
		17 Nov 2020 23:00:31
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 00:22:10
User entered 'Lower BACK PAIN' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:22:06
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User entered 'back pain'	(b) (4), (b) (6)	12 Oct 2020 11:44:00
		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '10'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'as needed (PRN)'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '29 Jul 2020'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:18:44
		17 Nov 2020 23:00:31
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 00:22:24
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:22:19
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 11:44:19
		20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:25:33

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:35:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:35:30
Data point term sent to Coder	System	20 Aug 2020 19:35:03
User entered 'duloxetine'	(b) (4), (b) (6)	20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'anxiety'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '60'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'once daily (QD)'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:34:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:34:22
User entered 'un UNK 2000'	(b) (4), (b) (6)	20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:34:22

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 10:14:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 10:14:32
	(b) (4)	
Data point term sent to Coder	System	06 Nov 2020 00:27:47
Coding entries removed.	Danuel Hamlin (b) (4)	06 Nov 2020 00:26:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:16:10
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:16:10
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 19:37:06
User entered 'gabapentin'	(b) (4), (b) (6)	20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS (rheumatoid, gout, osteoarthritis). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:18:57
		17 Nov 2020 23:00:31
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS (rheumatoid, gout, osteoarthritis). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Specific type of arthritis is unknown. ' (Site from DM).	Danuel Hamlin (b) (4)	06 Nov 2020 00:27:22
User entered 'BILATERAL KNEE ARTHRITIS' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:26:48
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS (rheumatoid, gout, osteoarthritis). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). User entered 'arthritis knees'	(b) (4), (b) (6)	21 Oct 2020 07:25:31
		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '300'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'three times daily (TID)'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:37:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:36:11
User entered 'un May 2020'	(b) (4), (b) (6)	20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:36:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
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)	06 Nov 2020 00:18:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 00:18:24
	(b) (4)	
Data point term sent to Coder	System	06 Nov 2020 00:17:39
Coding entries removed.	Danuel Hamlin (b) (4)	06 Nov 2020 00:17:12
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)	21 Aug 2020 05:14:18
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Aug 2020 05:14:18
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 19:37:07
User entered 'glipizide'	(b) (4), (b) (6)	20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Type II Diabetes' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:17:12
User entered 'T2DM'	(b) (4), (b) (6)	20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '5'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'twice daily (BID)'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:37:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:37:05
User entered 'un Jan 2020'	(b) (4), (b) (6)	20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:37:05

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLERTEC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:37:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:37:38
Data point term sent to Coder Coding entries removed.	System Danuel Hamlin (b) (4)	06 Nov 2020 00:17:37 06 Nov 2020 00:16:44
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLERTEC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:05:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:05:27
Data point term sent to Coder User entered 'allertec'	System (b) (4), (b) (6)	20 Aug 2020 19:39:10 20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Seasonal Allergic Rhinitis / Perennial Allergic Rhinitis' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	06 Nov 2020 00:16:44
User entered 'SAR/PAR'	(b) (4), (b) (6)	20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '10'		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'once daily (QD)'		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:43:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:38:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 19:38:16
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	20 Aug 2020 19:38:29
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 19:38:29
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	20 Aug 2020 19:38:16
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'		20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 19:38:16

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 00:31:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	21 Oct 2020 00:31:27
Data point term sent to Coder	System	21 Oct 2020 00:30:19
User entered 'Iron Supplement'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Anemia'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '325'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'every other day (QOD)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '16 Oct 2020'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 00:29:36

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: VICODIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:36:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:36:29
Data point term sent to Coder	System	06 Nov 2020 00:59:06
User entered 'Vicodin (325/5 mg)'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Post Gastric Bypass Surgery Pain'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'l'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'tablet (TABLET)'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'as needed (PRN)'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered empty.	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '02 Oct 2020'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '0'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered '03 Oct 2020'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:00:31
User entered 'No (N)'	Danuel Hamlin (b) (4)	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User entered empty.	System	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User entered empty.	System	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:23:05
User entered empty.	System	06 Nov 2020 00:58:07

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Feb 2021 21:40:05
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 Feb 2021 21:40:05
Data point term sent to Coder	System	22 Feb 2021 21:39:56
User entered 'Metformin'	(b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Type 2 Diabetes'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '1500'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'three times daily (TID)'	(b) (4) (d) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'un Feb 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered empty.	(b) (4) (d) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 21:39:11

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: OTHER DERMATOLOGICALS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 May 2021 18:06:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:06:20
Data point term sent to Coder	System	03 May 2021 17:24:51
User entered 'Dermal Filler'	(b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'Cosmetic'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'UKN'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
Query 'Data is required. Please complete.' answered with 'Data unavailable. Specifics of dermal filler are not known. ' (Site from System).	(b) (4) (b) (4), (b) (6)	03 May 2021 17:25:01
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 17:24:18
User entered empty.	(b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'Transdermal (TRANSDERMAL)'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered '0'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 17:24:18

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 17:24:18

US3462255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:38:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:29:24
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:43:39
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:25:44

US3462255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:38:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:44:13
User entered '02 Oct 2020'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:26:15

US3462255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:38:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:44:13
User entered 'Gastric Bypass Surgery'	Danuel Hamlin (b) (4) 	21 Oct 2020 00:26:15

US3462255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:38:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:44:13
User entered 'Medical History (MH)'	Danuel Hamlin (b) (4)	21 Oct 2020 00:26:15

US3462255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:38:14

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:44:13
User entered empty.	Danuel Hamlin (b) (4) 	21 Oct 2020 00:26:15

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'USA-US093-2020-MRNA-1273-P301000008'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Gregg'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Edward'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Lucksinger'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Kerwin'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '1900 Cypress Creek Rd'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'Cedar Park'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'TX'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '78613'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:44
User entered 'US'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 17:50:54
User entered '3'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
User entered '2'	System	07 Nov 2020 00:07:15
User entered '1'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'USA-US093-2020-MRNA-1273-P301000008'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Gregg'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Edward'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Lucksinger'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Kerwin'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '1900 Cypress Creek Rd'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'Cedar Park'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'TX'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '78613'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:44
User entered 'US'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 17:50:54
User entered '3'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
User entered '2'	System	07 Nov 2020 00:07:15
User entered '1'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:38:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
User entered '21/Oct/2020 21:07'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:38:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:44
User entered '1'		21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'USA-US093-2020-MRNA-1273-P301000008'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Gregg'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Edward'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Lucksinger'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Kerwin'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '1900 Cypress Creek Rd'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'Cedar Park'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'TX'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '78613'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:44
User entered 'US'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 17:50:54
User entered '3'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
User entered '2'	System	07 Nov 2020 00:07:15
User entered '1'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:38:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
User entered '06/Nov/2020 19:07'	System	07 Nov 2020 00:07:15

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:38:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:47:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
User entered 'I'		07 Nov 2020 00:07:15

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'USA-US093-2020-MRNA-1273-P301000008'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Gregg'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Edward'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Lucksinger'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Kerwin'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '1900 Cypress Creek Rd'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'Cedar Park'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'TX'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '78613'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:44
User entered 'US'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 17:50:54
User entered '3'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
User entered '2'	System	07 Nov 2020 00:07:15
User entered '1'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:38:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
User entered '29/Apr/2021 17:47'	(b) (4) System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:38:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'I'		29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'USA-US093-2020-MRNA-1273-P301000008'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Yes (Y)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'No (N)'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Gregg'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Edward'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
Un-reviewed for Safety.	System	29 Apr 2021 21:47:48
DataPoint Un-verified.	System	29 Apr 2021 21:47:48
Signature has been broken.	System	29 Apr 2021 21:47:48
User entered 'Lucksinger'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:14
User entered 'Kerwin'	System	21 Oct 2020 21:06:01

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '1900 Cypress Creek Rd'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'Cedar Park'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered 'TX'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:06:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:49:59
User entered '78613'	System	29 Apr 2021 21:47:48

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:08
Reviewed for Safety.		21 Oct 2020 21:07:44
User entered 'US'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 17:50:54
User entered '3'	System	29 Apr 2021 21:47:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:22:31
	(b) (4)	
User entered '2'	System	07 Nov 2020 00:07:15
User entered '1'	System	21 Oct 2020 21:07:34

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:38:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered '03/May/2021 13:50'	(b) (4) System	03 May 2021 17:50:54

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:38:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 May 2021 17:50:54