

US3462097 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:39:04

All time stamps listed in this document are displayed in GMT

US3462097

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

Participant ID

US3462097

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

US3462097

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3462097

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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 01:23:15

Generated On: 09 Jun 2021 17:39:04

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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1964
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 1964
Start Year (derived)	1964
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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	PERENNIAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1964
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 1964
Start Year (derived)	1964
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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	BILATERAL STRABISMUS
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN FEB 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2009
Start Year (derived)	2009
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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	ELEVATED PSA
Start date (dd MMM yyyy)	UN FEB 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)	FEB 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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	OCCASIONAL HEADACHES
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
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 01:23:15

Generated On: 09 Jun 2021 17:39:04

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	LEFT KNEE GANGLION CYST
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: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	OCCASIONAL BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
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 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	OCCASIONAL NECK PAIN
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 (13)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	LEFT ANTERIOR CRUCIATE LIGAMENT TEAR
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	LEFT MEDICAL MENISCUS TEAR
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	RIGHT KNEE BENIGN CYST
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1962
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 1962
Start Year (derived)	1962
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	LEFT KNEE RECONSTRUCTION SURGERY
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	RIGHT EYE STRABISMUS REPAIR
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	JAN 1965
Stop Year (derived)	1965

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Condition	RIGHT KNEE CYST REMOVAL
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:00 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:00
Height (<i>xxx.x</i>)	176 cm
Weight (<i>xxx.x</i>)	90.2 kg
BMI (<i>xxx.x</i>)	29.11932 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)	

US3462097

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:23:15

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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 01:23:16

Generated On: 09 Jun 2021 17:39:04

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 143567

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 01:23:16

Generated On: 09 Jun 2021 17:39:04

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 01:23:16

Generated On: 09 Jun 2021 17:39:04

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)	10 AUG 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:00
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

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)	10 AUG 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:30
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

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 01:23:16

Generated On: 09 Jun 2021 17:39:04

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 12:58 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 12:58

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 01:23:16

Generated On: 09 Jun 2021 17:39:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

12:40 (24 HR)

Collection date and time (derived)

10 AUG 2020 12:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	10 AUG 2020 12:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

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 17:39:04

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 13:33

PC Open Date & Time

10 AUG 2020 13:18

PC Close Date & Time

10 AUG 2020 15:48

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 98.2 °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	10 AUG 2020 21:32
PC Open Date & Time	10 AUG 2020 16:43
PC Close Date & Time	11 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 22:42

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

12 AUG 2020 20:04

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

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

13 AUG 2020 20:15

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

98.6 °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

14 AUG 2020 20:43

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

98.2 °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

15 AUG 2020 21:06

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 AUG 2020 23:06

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 13:35

PC Open Date & Time

10 AUG 2020 13:18

PC Close Date & Time

10 AUG 2020 15:48

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

10 AUG 2020 21:33

PC Open Date & Time

10 AUG 2020 16:43

PC Close Date & Time

11 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

11 AUG 2020 22:43

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

12 AUG 2020 20:05

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

13 AUG 2020 20:15

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

14 AUG 2020 20:44

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

15 AUG 2020 21:06

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

16 AUG 2020 23:06

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 13:36
PC Open Date & Time	10 AUG 2020 13:18
PC Close Date & Time	10 AUG 2020 15:48

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 21:34
PC Open Date & Time	10 AUG 2020 16:43
PC Close Date & Time	11 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 ☒

PRODUCTION RELEASE (v12.003

62 of 2036

EAB) (1725)

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

64 of 2036

EAB) (1725)

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:06
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

66 of 2036

EAB) (1725)

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 20:16
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

68 of 2036

EAB) (1725)

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:45
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 ☒

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:07
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

72 of 2036

EAB) (1725)

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 23:07
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3462097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:09
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:17
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3462097

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

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.

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:43 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 12:43

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

What was the frequency of the study treatment dosing? ONCE

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

US3462097

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	12:37 (24 HR)
Collection date and time (derived)	14 SEP 2020 12:37

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:33	14 SEP 2020 12:33
Nasopharyngeal Swab 2	No		

US3462097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

99.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 14 SEP 2020 13:12

PC Open Date & Time 14 SEP 2020 13:03

PC Close Date & Time 14 SEP 2020 15:33

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 98.0 °F

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

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

PC Time Stamp	14 SEP 2020 21:24
PC Open Date & Time	14 SEP 2020 16:28
PC Close Date & Time	15 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	15 SEP 2020 19:15
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 19:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

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):

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

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

PC Time Stamp 17 SEP 2020 20:28

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

98.3 °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

18 SEP 2020 19:38

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 19:24

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

99.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 19:10

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 13:13

PC Open Date & Time

14 SEP 2020 13:03

PC Close Date & Time

14 SEP 2020 15:33

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:25

PC Open Date & Time

14 SEP 2020 16:28

PC Close Date & Time

15 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 19:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 19:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 20:29

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 19:38

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 19:25

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 19:11

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 13:14
PC Open Date & Time	14 SEP 2020 13:03
PC Close Date & Time	14 SEP 2020 15:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 21:28
PC Open Date & Time	14 SEP 2020 16:28
PC Close Date & Time	15 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 ☒

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

110 of 2036

EAB) (1725)

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:10
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

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 ☒

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 20:30
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

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)

114 of 2036

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 19:39
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 ☒

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US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:25
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

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 ☒

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 9

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:15

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

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) _____

US3462097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

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.

US3462097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

11:30 (24 HR)

Collection date and time (derived)

8 OCT 2020 11:30

US3462097

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:16

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 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 OCT 2020 21:41:36
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

19 OCT 2020 12:04:49

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 <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"/>

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 05:53:16

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

15 NOV 2020 07:12:52

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 10:22:26

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 20:58:03
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 08:42:15

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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	10 DEC 2020 13:00:47
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

16 DEC 2020 08:19:46

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

23 DEC 2020 16:11:30

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

31 DEC 2020 12:16:36

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 <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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 06:28:55

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 <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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

04 MAR 2021 12:27:25

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

10 MAR 2021 14:31:16

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 17:15:20
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 MAR 2021 09:14:20
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 14:10:25

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

11 APR 2021 20:56:27

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

14 APR 2021 11:56:08

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 11:47:36

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 05:39:18

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 <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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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="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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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="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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Patient Cloud Open Date & Time	15 SEP 2021 00:01
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Patient Cloud Close Date & Time	19 SEP 2021 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Patient Cloud Open Date & Time	27 OCT 2021 00:01
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Patient Cloud Close Date & Time	31 OCT 2021 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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°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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 FEB 2022 00:01
Patient Cloud Close Date & Time	13 FEB 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 <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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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°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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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="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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Patient Cloud Open Date & Time	20 APR 2022 00:01
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Patient Cloud Close Date & Time	24 APR 2022 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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="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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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="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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

Patient Cloud Open Date & Time	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:39:04

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 12:28:03

US3462097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462097

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:06:33

Generated On: 09 Jun 2021 17:39:04

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

Visit date (dd MMM yyyy)	16 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:04:41

Generated On: 09 Jun 2021 17:39:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:37 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 09:37
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	57 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3462097

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:06:33

Generated On: 09 Jun 2021 17:39:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3462097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:06:33

Generated On: 09 Jun 2021 17:39:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	10:00 (24 HR)
Collection date and time (derived)	16 MAR 2021 10:00

US3462097

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:06:33

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462097

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462097

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:39:04

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3462097

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 21:56:44

Generated On: 09 Jun 2021 17:39:04

Date of updated informed consent (*dd MMM yyyy*) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3462097

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00-23:59)	01:51 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	12 JAN 2021 01:51
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US3462097

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	01:47
Collection Date and Time (derived)	12 JAN 2021 01:47

US3462097

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 19:06:33

Generated On: 09 Jun 2021 17:39:04

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

AEID	USA-US093-2021-MRNA-1273-P30 1000008
Adverse event	PROSTATE CANCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

PATIENT CAME IN FOR D209.
REPORTED DIAGNOSIS OF
PROSTATE CANCER,
RECORDED DIAGNOSIS AS AE,
PE DONE AND VITALS
CHECKED, WILL UPDATE
WHEN WE HAVE MORE
INFORMATION DUE TO IT ONLY
BEEN LESS THEN 2 MONTHS
SUBJECT HAS NO TREATMENT
PLAN YET.

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)	
--	--

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 180

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) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
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 (2)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

Name of Medication SYMBICORT 160/4.5

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL HEADACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

	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 1990	
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 (4)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL HEADACHES

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

	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 1990	
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 (5)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication POST-DOSE FEVER

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

	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)	15 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	15 SEP 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication POST-DOSE MUSCLE ACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 19:42:52

Generated On: 09 Jun 2021 17:39:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:42:53

Generated On: 09 Jun 2021 17:39:04

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:39:04

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

US3462097

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:39:04

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 ☐

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 22:31:43

Generated On: 09 Jun 2021 17:39:04

SAEID	USA-US093-2021-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 22:31:43

Generated On: 09 Jun 2021 17:39:04

SAEID	USA-US093-2021-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	31/MAR/2021 11:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 22:31:43

Generated On: 09 Jun 2021 17:39:04

SAEID	USA-US093-2021-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	13/APR/2021 15:17
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

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 22:31:43

Generated On: 09 Jun 2021 17:39:04

SAEID	USA-US093-2021-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	22/APR/2021 08:27
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

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 22:31:43

Generated On: 09 Jun 2021 17:39:04

SAEID	USA-US093-2021-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	26/APR/2021 10:22
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

US3462097 (Prod: Crisor, LLC)

US3462097

Form: Participant Creation

Generated On: 09 Jun 2021 17:39:04

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:43:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'US3462097'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:50

US3462097

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:05:49
User entered 'Yes (Y)'		10 Aug 2020 20:27:43

US3462097

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:05:52
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:51

US3462097

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:05:51
User entered 'Clinic (Clinic)'		10 Aug 2020 20:27:43

US3462097

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'SCRN'	System	10 Aug 2020 20:27:43

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User closed query 'Please provide demographic page in source document.' (Site from CRA).	(b) (4)	19 Nov 2020 00:16:39
Query 'Please provide demographic page in source document.' answered with 'Demographics are recorded on Registration page 1.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:15:02
User opened query 'Please provide demographic page in source document.' (Site from CRA).		22 Sep 2020 23:18:35
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:52

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '64'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'YEARS'	System	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '64'	System	10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered 'Male (M)'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered 'l'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered empty.	(b) (4)	
	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:28:03

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:09:05
User entered '10 Aug 2020'		10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Aug 2020'	System	10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2020'	System	10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:10:33
Query 'Please verify if this was an amendment 2 of 3 and update accordingly.' canceled (Site from CRA).		22 Sep 2020 23:10:30
User opened query 'Please verify if this was an amendment 2 of 3 and update accordingly.' (Site from CRA).		22 Sep 2020 23:09:03
User entered 'Amendment 2 (2)'		10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:09:07
User entered 'Yes (Y)'		10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:09:08
User entered empty.		10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:09:11
User entered empty.		10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:09:14
User entered 'No (N)'		10 Aug 2020 20:27:58

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:09:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:51

US3462097

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'I'	System	10 Aug 2020 20:28:06

US3462097

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:11:50
User entered 'Yes (Y)'		10 Aug 2020 20:28:06

US3462097

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:39:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:21:20
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:14

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User closed query 'Please enter all MH in eCRF.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:16:56
Query 'Please enter all MH in eCRF.' answered with 'Entered.' (Site from CRA).		23 Sep 2020 15:19:56
User opened query 'Please enter all MH in eCRF.' (Site from CRA).		22 Sep 2020 23:33:46
DataPoint Verified.		22 Sep 2020 23:21:48
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) (b) (4)	11 Aug 2020 20:30:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:30:15
Data point term sent to Coder	System	11 Aug 2020 20:29:19
User entered 'SEASONAL ALLERGIC RHINITIS'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:21:57
User entered 'UN UNK 1964'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:21:59
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:06
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:02
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:04
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1964'	System	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1964'	System	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:28:43

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis perennial, LLT: Perennial allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:30:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:30:15
Data point term sent to Coder	System	11 Aug 2020 20:29:21
User entered 'PERENNIAL ALLERGIC RHINITIS'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:40
User entered 'UN UNK 1964'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:41
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:43
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:44
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:22:47
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1964'	System	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1964'	System	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:28:57

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:08
User coded data point as SOC: Eye disorders, HLGT: Ocular neuromuscular disorders, HLT: Ocular nerve and muscle disorders, PT: Strabismus, LLT: Strabismus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:27:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:27:21
Data point term sent to Coder	System	11 Aug 2020 20:30:22
User entered 'BILATERAL STRABISMUS'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:09
User entered 'UN UNK 1965'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:11
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:15
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:18
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1965'	System	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1965'	System	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:29:42

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:19:57
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'CM added.' (Site from DM).		09 Oct 2020 16:35:53
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		01 Oct 2020 08:10:06
DataPoint Verified.		22 Sep 2020 23:23:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:31:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:31:17
Data point term sent to Coder	System	11 Aug 2020 20:30:25
User entered 'ASTHMA'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:31
User entered 'UN UNK 1965'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:33
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:34
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:36
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:38
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1965'	System	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1965'	System	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:29:55

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:54:17
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Patient reports no med taken for this condition.' (Site from DM).		09 Oct 2020 16:36:12
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		01 Oct 2020 08:10:24
DataPoint Verified.		22 Sep 2020 23:23:54
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:32:18
Data point term sent to Coder	System	11 Aug 2020 20:31:25
User entered 'HYPERTENSION'	Danuel Hamlin (b) (4)	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:56
User entered 'UN Feb 2009'	Danuel Hamlin (b) (4)	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:57
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:23:59
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:01
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:03
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Feb 2009'	System	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2009'	System	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:30:27

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:15
User coded data point as SOC: Investigations, HLT: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: PSA increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:32:18
Data point term sent to Coder	System	11 Aug 2020 20:31:29
User entered 'ELEVATED PSA'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:32
User entered 'UN Feb 2010'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:35
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:37
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:41
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:24:44
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Feb 2010'	System	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2010'	System	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:03

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 13:15:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 13:15:50
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:10
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 23:25:04
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:32:18
Data point term sent to Coder	System	11 Aug 2020 20:31:30
User entered 'OCCASIONAL HEADACHES'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:25:06
User entered 'UN UNK 1989'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:25:09
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:25:11
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:25:14
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:25:17
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1989'	System	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1989'	System	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:21

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:25:56
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) (b) (4)	11 Aug 2020 20:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:33:21
Data point term sent to Coder	System	11 Aug 2020 20:32:32
User entered 'HYPERCHOLESTEROLEMIA'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:25:59
User entered 'UN UNK 2009'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:01
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:04
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:11
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:13
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2009'	System	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2009'	System	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:36

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:33:21
Data point term sent to Coder	System	11 Aug 2020 20:32:32
User entered 'BILATERAL KNEE PAIN'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:29
User entered 'UN UNK 1987'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:31
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:33
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:36
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:26:38
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1987'	System	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1987'	System	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:31:55

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:27:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovial cyst, LLT: Ganglion cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:27:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:27:18
Data point term sent to Coder	System	11 Aug 2020 20:32:33
User entered 'LEFT KNEE GANGLION CYST'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:27:50
User entered 'UN UNK 2009'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:27:47
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:27:57
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:27:53
User entered 'UN UNK 2009'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:27:55
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2009'	System	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2009'	System	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2009'	System	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2009'	System	11 Aug 2020 20:32:11

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:28:58
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: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:21:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:21:18
Data point term sent to Coder	System	11 Aug 2020 20:32:33
User entered 'OCCASIONAL BACK PAIN'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:02
User entered 'UN UNK 2012'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:00
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:04
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:06
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:08
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2012'	System	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2012'	System	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:32:24

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:27
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: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 09:56:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 09:56:22
Data point term sent to Coder	System	11 Aug 2020 20:33:34
User entered 'OCCASIONAL NECK PAIN'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:29
User entered 'UN UNK 2010'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:31
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:33
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:35
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:29:37
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2010'	System	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2010'	System	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:32:42

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:34:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:34:10
Data point term sent to Coder	System	11 Aug 2020 20:33:35
User entered 'LEFT anterior cruciate ligament TEAR'	Danuel Hamlin (b) (4)	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:24
User entered 'UN UNK 1987'	Danuel Hamlin (b) (4)	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:25
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:27
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).		23 Oct 2020 11:20:53
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' answered with 'Corrected.' (Site from DM).		09 Oct 2020 16:37:39
DataPoint Un-verified.		09 Oct 2020 16:37:34
User entered 'UN UNK 1987' reason for change: Data Entry Error		09 Oct 2020 16:37:34
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).		01 Oct 2020 08:11:07
DataPoint Verified.		22 Sep 2020 23:30:29
User entered 'UN Jan 2016'	Danuel Hamlin (b) (4)	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:31
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1987'	System	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1987'	System	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1987'	System	09 Oct 2020 16:37:34
User entered 'Jan 2016'	System	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1987'	System	09 Oct 2020 16:37:34
User entered '2016'	System	11 Aug 2020 20:33:18

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:46
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) (b) (4)	14 Aug 2020 12:20:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:20:25
Data point term sent to Coder	System	11 Aug 2020 20:34:38
User entered 'LEFT MEDICAL MENISCUS TEAR'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:49
User entered 'UN UNK 1987'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:30:56
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:01
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).		23 Oct 2020 11:21:05
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' answered with 'Corrected.' (Site from DM).		09 Oct 2020 16:37:56
DataPoint Un-verified.		09 Oct 2020 16:37:50
User entered 'UN UNK 1987' reason for change: Data Entry Error		09 Oct 2020 16:37:50
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).		01 Oct 2020 08:11:27
DataPoint Verified.		22 Sep 2020 23:31:05
User entered 'UN Jan 2016'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:15
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1987'	System	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1987'	System	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1987'	System	09 Oct 2020 16:37:50
User entered 'Jan 2016'	System	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1987'	System	09 Oct 2020 16:37:50
User entered '2016'	System	11 Aug 2020 20:34:04

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Mass conditions NEC, PT: Cyst, LLT: Cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:32:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:32:51
Data point term sent to Coder	System	11 Aug 2020 20:35:39
User entered 'RIGHT KNEE BENIGN CYST'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:37
User entered 'UN UNK 2011'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:41
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:45
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:49
User entered 'UN UNK 2011'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:31:51
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2011'	System	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2011'	System	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2011'	System	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2011'	System	11 Aug 2020 20:34:44

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:19:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:19:42
Data point term sent to Coder	System	23 Sep 2020 15:18:16
User entered 'penicillin allergy'	(b) (4), (b) (6)	23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un UNK 1962'		23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'Yes (Y)'		23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered empty.		23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1962'	System	23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1962'	System	23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	23 Sep 2020 15:17:19

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:24:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:24:45
Data point term sent to Coder	System	23 Sep 2020 15:18:18
User entered 'cortisone injection allergy'	(b) (4), (b) (6)	23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un Apr 2015'		23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'Yes (Y)'		23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered empty.		23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Apr 2015'	System	23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2015'	System	23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	23 Sep 2020 15:17:51

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).		04 Nov 2020 11:50:09
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		21 Oct 2020 04:53:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Joint arthroplasty, LLT: Joint reconstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:34:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:34:55
Data point term sent to Coder	System	23 Sep 2020 15:18:22
User entered 'left knee reconstruction surgery'	(b) (4), (b) (6)	23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un UNK 1987'		23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'No (N)'		23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un UNK 1987'		23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1987'	System	23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1987'	System	23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1987'	System	23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1987'	System	23 Sep 2020 15:18:15

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Orbit and globe therapeutic procedures, PT: Strabismus correction, LLT: Strabismus correction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:35:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:35:38
Data point term sent to Coder	System	23 Sep 2020 15:19:24
User entered 'right eye strabismus repair'	(b) (4), (b) (6)	23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un UNK 1965'		23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'No (N)'		23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un UNK 1965'		23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1965'	System	23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1965'	System	23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 1965'	System	23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '1965'	System	23 Sep 2020 15:18:38

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cyst removal, LLT: Cyst removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:35:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:35:38
Data point term sent to Coder	System	23 Sep 2020 15:19:25
User entered 'right knee cyst removal'	(b) (4), (b) (6)	23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un UNK 2011'		23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'No (N)'		23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un UNK 2011'		23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2011'	System	23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2011'	System	23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2011'	System	23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2011'	System	23 Sep 2020 15:18:58

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).		04 Nov 2020 11:50:21
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		21 Oct 2020 04:53:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:20:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:20:46
Data point term sent to Coder	System	23 Sep 2020 15:19:36
User entered 'left knee replacement'	(b) (4), (b) (6)	23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un Jan 2016'		23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'No (N)'		23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered 'un Jan 2016'		23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:27
User entered '0'		23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2016'	System	23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2016'	System	23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'Jan 2016'	System	23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:39:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '2016'	System	23 Sep 2020 15:19:23

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:34:56
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:34:58
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:35:00
User entered '12:00'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '10 Aug 2020 12:00'	System	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:35:18
User entered '176' cm	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07
DataPoint set to visible.	System	10 Aug 2020 20:28:06

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:35:22
User entered '90.2' kg	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07
DataPoint set to visible.	System	10 Aug 2020 20:28:06

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
Amendment Manager: User entered '29.11932'	System	16 Sep 2020 23:50:23
User entered '29.1'	System	11 Aug 2020 20:36:07
DataPoint set to visible.	System	10 Aug 2020 20:28:06

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'kg/m2'	System	11 Aug 2020 20:36:07
DataPoint set to visible.	System	10 Aug 2020 20:28:06

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:38
DataPoint Un-verified.		23 Sep 2020 16:38:34
User entered missing code ND - Not Done; reason fo change Data Entry Error		23 Sep 2020 16:38:34
DataPoint Verified.		22 Sep 2020 23:35:28
User entered '37.2' C	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:38
User closed query 'Route in source document does not match with eCRF. Please verify and update accordingly.' (Site from CRA).		19 Nov 2020 00:17:35
User entered empty; reason for change Data Entry Error		23 Sep 2020 16:38:34
Query 'Route in source document does not match with eCRF. Please verify and update accordingly.' answered with 'Corrected.' (Site from CRA).		23 Sep 2020 15:21:08
User entered 'Other (Other)' reason for change: Data Entry Error		23 Sep 2020 15:20:51
User opened query 'Route in source document does not match with eCRF. Please verify and update accordingly.' (Site from CRA).		22 Sep 2020 23:36:22
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:38
User entered empty; reason for change Data Entry Error		23 Sep 2020 16:38:34
DataPoint Un-verified.		23 Sep 2020 15:20:51
User entered 'tympanic' reason for change: Data Entry Error		23 Sep 2020 15:20:51
DataPoint Verified.		22 Sep 2020 23:36:28
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:38
DataPoint Un-verified.		23 Sep 2020 16:38:34
User entered missing code ND - Not Done; reason for change Data Entry Error		23 Sep 2020 16:38:34
DataPoint Verified.		22 Sep 2020 23:36:37
User entered '60'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'bpm'	System	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:38
DataPoint Un-verified.		23 Sep 2020 16:38:34
User entered missing code ND - Not Done; reason for change Data Entry Error		23 Sep 2020 16:38:34
DataPoint Verified.		22 Sep 2020 23:36:40
User entered '15'	Daniel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'breaths/min'	System	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:38
DataPoint Un-verified.		23 Sep 2020 16:38:34
User entered missing code ND - Not Done; reason for change Data Entry Error		23 Sep 2020 16:38:34
DataPoint Verified.		22 Sep 2020 23:36:44
User entered '120'	Daniel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'mmHg'	System	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:17:38
DataPoint Un-verified.		23 Sep 2020 16:38:34
User entered missing code ND - Not Done; reason fo change Data Entry Error		23 Sep 2020 16:38:34
DataPoint Verified.		22 Sep 2020 23:36:45
User entered '84'	Daniel Hamlin (b) (4)	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'mmHg'	System	11 Aug 2020 20:36:07

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58

US3462097

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58

US3462097

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:37:55
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:14

US3462097

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
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 11:27:35
DataPoint Verified.		22 Sep 2020 23:38:05
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 19:50:15
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:14

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:39:41
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:39:43
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:39:48
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:39:50
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:39:53
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:39:57
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:39:59
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:02
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:04
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:09
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:12
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:20
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:22
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered 'I'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:26
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:28
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:30
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:33
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:35
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:40:38
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:36:33

US3462097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:41:06
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:52

US3462097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:41:08
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:52

US3462097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:41:10
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:52

US3462097

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'VISIT1'	System	11 Aug 2020 20:38:52

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:41:44
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:24:26

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:42:36
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:22:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:22:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 19:24:26
User entered '143567' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:24:26

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:49:14
DataPoint Un-verified.		22 Sep 2020 23:45:02
DataPoint Verified.		22 Sep 2020 23:42:39
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:24:26

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

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)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:49:20
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:14

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

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)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:49:28
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:14

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:49:42
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:14

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:49:45
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:14

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:49:47
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:14

US3462097

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:04

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:49:51
User entered 'No (N)'		21 Sep 2020 15:22:25
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:16:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:18:11

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
User entered missing code ND - Not Done; reason for change Data Entry Error		22 Sep 2020 21:38:47
User entered '176' cm	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
User entered missing code ND - Not Done; reason for change Data Entry Error		22 Sep 2020 21:38:47
User entered '90.2' kg	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
User entered missing code ND - Not Done; reason for change Data Entry Error		22 Sep 2020 21:38:47
User entered '176' cm	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
User entered missing code ND - Not Done; reason for change Data Entry Error		22 Sep 2020 21:38:47
User entered '90.2' kg	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered 'Yes (Y)' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:50:34
User entered 'No (N)' reason for change: Data Entry Error		22 Sep 2020 19:33:41
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered '10 Aug 2020' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:50:39
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered '12:00' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:50:42
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered '12:00'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '10 Aug 2020 12:00'	System	23 Sep 2020 16:38:19
User entered empty.	System	22 Sep 2020 19:33:41
User entered '10 Aug 2020 12:00'	System	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered '37.2' C reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:50:44
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered '37.2' C	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered 'Other (Other)' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:50:45
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered 'tympanic' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:52:58
DataPoint Un-verified.		22 Sep 2020 23:52:55
DataPoint Verified.		22 Sep 2020 23:50:48
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered '60' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:52:57
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered '60'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'bpm'	System	23 Sep 2020 16:38:19
User entered empty.	System	22 Sep 2020 19:33:41
User entered 'bpm'	System	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered '15' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:53:00
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered '15'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'breaths/min'	System	23 Sep 2020 16:38:19
User entered empty.	System	22 Sep 2020 19:33:41
User entered 'breaths/min'	System	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered '120' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:53:02
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered '120'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'mmHg'	System	23 Sep 2020 16:38:19
User entered empty.	System	22 Sep 2020 19:33:41
User entered 'mmHg'	System	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 16:38:19
User entered '84' reason for change: Data Entry Error		23 Sep 2020 16:38:19
DataPoint Verified.		22 Sep 2020 23:53:04
User entered empty; reason for change Data Entry Error		22 Sep 2020 19:33:41
User entered '84'	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'mmHg'	System	23 Sep 2020 16:38:19
User entered empty.	System	22 Sep 2020 19:33:41
User entered 'mmHg'	System	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
User entered missing code ND - Not Done; reason for change Data Entry Error		22 Sep 2020 21:38:47
User entered '176' cm	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
User entered missing code ND - Not Done; reason for change Data Entry Error		22 Sep 2020 21:38:47
User entered '90.2' kg	Danuel Hamlin (b) (4)	11 Aug 2020 20:37:16

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:54:32
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:54:34
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:54:38
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		18 Aug 2020 10:55:36
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 20:38:39
User entered '13:30'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '10 Aug 2020 13:30'	System	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:54:37
User entered '36.9' C	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
User closed query 'Route in source document does not match with eCRF. Please verify and update accordingly.' (Site from CRA).		19 Nov 2020 00:18:00
Query 'Route in source document does not match with eCRF. Please verify and update accordingly.' answered with 'Corrected.' (Site from CRA).		23 Sep 2020 15:22:04
User entered 'Other (Other)' reason for change: Data Entry Error		23 Sep 2020 15:21:53
User opened query 'Route in source document does not match with eCRF. Please verify and update accordingly.' (Site from CRA).		22 Sep 2020 23:55:45
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:03
DataPoint Un-verified.		23 Sep 2020 15:21:53
User entered 'tympanic' reason for change: Data Entry Error		23 Sep 2020 15:21:53
DataPoint Verified.		22 Sep 2020 23:55:48
User entered empty.	Daniel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:55:51
User entered '56'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'bpm'	System	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:55:54
User entered '15'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'breaths/min'	System	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:55:57
User entered '116'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'mmHg'	System	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:55:59
User entered '80'	Danuel Hamlin (b) (4)	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'mmHg'	System	11 Aug 2020 20:38:39

US3462097

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:56:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:26

US3462097

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:56:54
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:26

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:57:41
User entered 'Yes (Y)'		10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:57:47
User entered empty.		10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

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 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:57:45
User entered empty.		10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:57:28
User entered '10 Aug 2020'		10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:57:29
User entered '12:58'		10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '10 Aug 2020 12:58'	System	10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:57:32
User entered 'Left Arm (LEFT ARM)'		10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		22 Sep 2020 23:57:34
User entered 'ONCE'	System	10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 20:28:35

US3462097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:58:11
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:40

US3462097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:58:15
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:40

US3462097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:58:17
User entered '12:40'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:40

US3462097

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '10 Aug 2020 12:40'	System	11 Aug 2020 20:39:40

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:39:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
DataPoint Verified.		20 Apr 2021 20:46:17
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
User entered '10 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:58:37
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:58:39
User entered '12:35'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered '10 Aug 2020 12:35'	System	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:59:11
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:59:12
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered empty.	System	11 Aug 2020 20:39:53

US3462097

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:59:36
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 20:39:58

US3462097

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:58
User entered 'I'	System	11 Aug 2020 20:39:58

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:32:57', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c64b2130-4556-469f-8cb1-9c334b09a986'	System	10 Aug 2020 20:33:52
User entered 'Yes (Y)'	System	10 Aug 2020 20:33:52

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:33:19', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c64b2130-4556-469f-8cb1-9c334b09a986'	System	10 Aug 2020 20:33:52
User entered '98.4'	System	10 Aug 2020 20:33:52

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:33:25', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c64b2130-4556-469f-8cb1-9c334b09a986'	System	10 Aug 2020 20:33:52
User entered 'No (N)'	System	10 Aug 2020 20:33:52

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:33:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c64b2130-4556-469f-8cb1-9c334b09a986'	System	10 Aug 2020 20:33:52
User entered '10 Aug 2020 13:33'	System	10 Aug 2020 20:33:52

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 13:18'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 15:48'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:32:11', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5171d0b2-9c2b-4383-ba71-f827548d2b7a'	System	11 Aug 2020 04:32:38
User entered 'Yes (Y)'	System	11 Aug 2020 04:32:38

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:32:20', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5171d0b2-9c2b-4383-ba71-f827548d2b7a'	System	11 Aug 2020 04:32:38
User entered '98.2'	System	11 Aug 2020 04:32:38

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:32:27', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5171d0b2-9c2b-4383-ba71-f827548d2b7a'	System	11 Aug 2020 04:32:38
User entered 'No (N)'	System	11 Aug 2020 04:32:38

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:32:34', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5171d0b2-9c2b-4383-ba71-f827548d2b7a'	System	11 Aug 2020 04:32:38
User entered '10 Aug 2020 21:32'	System	11 Aug 2020 04:32:38

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 16:43'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 2'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:41:38', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'cbf5bafd-3fc4-4621-8e69-899facb0fdbe'	System	12 Aug 2020 05:42:29
User entered 'Yes (Y)'	System	12 Aug 2020 05:42:29

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:42:04', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'cbf5bafd-3fc4-4621-8e69-899facb0fdbe'	System	12 Aug 2020 05:42:29
User entered '97.9'	System	12 Aug 2020 05:42:29

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:42:20', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'cbf5bafd-3fc4-4621-8e69-899facb0fdbbe'	System	12 Aug 2020 05:42:29
User entered 'No (N)'	System	12 Aug 2020 05:42:29

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:42:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'cbf5bafd-3fc4-4621-8e69-899facb0fdbe'	System	12 Aug 2020 05:42:29
User entered '11 Aug 2020 22:42'	System	12 Aug 2020 05:42:29

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 3'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:04:21', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e145b42-0c6f-45ba-b2bf-f26cfdbb65aa'	System	13 Aug 2020 03:04:47
User entered 'Yes (Y)'	System	13 Aug 2020 03:04:47

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:04:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e145b42-0c6f-45ba-b2bf-f26cfdbb65aa'	System	13 Aug 2020 03:04:47
User entered '98.2'	System	13 Aug 2020 03:04:47

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:04:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e145b42-0c6f-45ba-b2bf-f26cfdbb65aa'	System	13 Aug 2020 03:04:47
User entered 'No (N)'	System	13 Aug 2020 03:04:47

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:04:43', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e145b42-0c6f-45ba-b2bf-f26cfdbb65aa'	System	13 Aug 2020 03:04:47
User entered '12 Aug 2020 20:04'	System	13 Aug 2020 03:04:47

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 4'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:14:39', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '93bb2ee2-b15c-425b-861d-7d6161d7c33a'	System	14 Aug 2020 03:15:08
User entered 'Yes (Y)'	System	14 Aug 2020 03:15:08

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:14:47', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '93bb2ee2-b15c-425b-861d-7d6161d7c33a'	System	14 Aug 2020 03:15:08
User entered '99.0'	System	14 Aug 2020 03:15:08

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:14:51', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '93bb2ee2-b15c-425b-861d-7d6161d7c33a'	System	14 Aug 2020 03:15:08
User entered 'No (N)'	System	14 Aug 2020 03:15:08

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:15:04', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '93bb2ee2-b15c-425b-861d-7d6161d7c33a'	System	14 Aug 2020 03:15:08
User entered '13 Aug 2020 20:15'	System	14 Aug 2020 03:15:08

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 5'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:43:24', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '73513f67-4d94-499c-a93e-ddf159920d34'	System	15 Aug 2020 03:43:57
User entered 'Yes (Y)'	System	15 Aug 2020 03:43:57

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:43:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '73513f67-4d94-499c-a93e-ddf159920d34'	System	15 Aug 2020 03:43:57
User entered '98.6'	System	15 Aug 2020 03:43:57

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:43:43', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '73513f67-4d94-499c-a93e-ddf159920d34'	System	15 Aug 2020 03:43:57
User entered 'No (N)'	System	15 Aug 2020 03:43:57

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:43:52', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '73513f67-4d94-499c-a93e-ddf159920d34'	System	15 Aug 2020 03:43:57
User entered '14 Aug 2020 20:43'	System	15 Aug 2020 03:43:57

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 6'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:14', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a62e3c11-647a-4ea2-b532-f8823806a797'	System	16 Aug 2020 04:06:34
User entered 'Yes (Y)'	System	16 Aug 2020 04:06:34

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:21', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a62e3c11-647a-4ea2-b532-f8823806a797'	System	16 Aug 2020 04:06:34
User entered '98.2'	System	16 Aug 2020 04:06:34

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:25', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a62e3c11-647a-4ea2-b532-f8823806a797'	System	16 Aug 2020 04:06:34
User entered 'No (N)'	System	16 Aug 2020 04:06:34

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:29', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a62e3c11-647a-4ea2-b532-f8823806a797'	System	16 Aug 2020 04:06:34
User entered '15 Aug 2020 21:06'	System	16 Aug 2020 04:06:34

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 7'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:05:02', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c04cfc6-57d3-48dd-9dc5-7455d7641f14'	System	17 Aug 2020 06:06:25
User entered 'Yes (Y)'	System	17 Aug 2020 06:06:25

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:07', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c04cfc6-57d3-48dd-9dc5-7455d7641f14'	System	17 Aug 2020 06:06:25
User entered '97.6'	System	17 Aug 2020 06:06:25

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:12', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c04cfc6-57d3-48dd-9dc5-7455d7641f14'	System	17 Aug 2020 06:06:25
User entered 'No (N)'	System	17 Aug 2020 06:06:25

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:20', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c04cfc6-57d3-48dd-9dc5-7455d7641f14'	System	17 Aug 2020 06:06:25
User entered '16 Aug 2020 23:06'	System	17 Aug 2020 06:06:25

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:34:16', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a553d4a4-9929-4395-b2e8-d4d20b5b5634'	System	10 Aug 2020 20:35:31
User entered 'None (1)'	System	10 Aug 2020 20:35:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:34:58', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a553d4a4-9929-4395-b2e8-d4d20b5b5634'	System	10 Aug 2020 20:35:31
User entered 'No (N)'	System	10 Aug 2020 20:35:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:35:06', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a553d4a4-9929-4395-b2e8-d4d20b5b5634'	System	10 Aug 2020 20:35:31
User entered 'No (N)'	System	10 Aug 2020 20:35:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:35:16', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a553d4a4-9929-4395-b2e8-d4d20b5b5634'	System	10 Aug 2020 20:35:31
User entered 'None (1)'	System	10 Aug 2020 20:35:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:35:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a553d4a4-9929-4395-b2e8-d4d20b5b5634'	System	10 Aug 2020 20:35:31
User entered '10 Aug 2020 13:35'	System	10 Aug 2020 20:35:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 13:18'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 15:48'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:32:56', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b723b45-a582-497f-91e3-8db1eafdfbfb'	System	11 Aug 2020 04:33:33
User entered 'None (1)'	System	11 Aug 2020 04:33:33

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:02', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b723b45-a582-497f-91e3-8db1eafdfbfb'	System	11 Aug 2020 04:33:33
User entered 'No (N)'	System	11 Aug 2020 04:33:33

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b723b45-a582-497f-91e3-8db1eafdfbfb'	System	11 Aug 2020 04:33:33
User entered 'No (N)'	System	11 Aug 2020 04:33:33

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:23', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b723b45-a582-497f-91e3-8db1eafdfbfb'	System	11 Aug 2020 04:33:33
User entered 'None (1)'	System	11 Aug 2020 04:33:33

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:29', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b723b45-a582-497f-91e3-8db1eafdfbfb'	System	11 Aug 2020 04:33:33
User entered '10 Aug 2020 21:33'	System	11 Aug 2020 04:33:33

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 16:43'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 2'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:42:46', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7b0e6c1f-2c56-454a-ab7f-7e49e0ac3019'	System	12 Aug 2020 05:43:31
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 05:43:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7b0e6c1f-2c56-454a-ab7f-7e49e0ac3019'	System	12 Aug 2020 05:43:31
User entered 'No (N)'	System	12 Aug 2020 05:43:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:14', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7b0e6c1f-2c56-454a-ab7f-7e49e0ac3019'	System	12 Aug 2020 05:43:31
User entered 'No (N)'	System	12 Aug 2020 05:43:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:23', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7b0e6c1f-2c56-454a-ab7f-7e49e0ac3019'	System	12 Aug 2020 05:43:31
User entered 'None (1)'	System	12 Aug 2020 05:43:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:27', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7b0e6c1f-2c56-454a-ab7f-7e49e0ac3019'	System	12 Aug 2020 05:43:31
User entered '11 Aug 2020 22:43'	System	12 Aug 2020 05:43:31

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 3'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:04:54', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '43097d6b-73f5-4456-bd5c-5fb75bb170ed'	System	13 Aug 2020 03:05:44
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 03:05:44

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:05:24', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '43097d6b-73f5-4456-bd5c-5fb75bb170ed'	System	13 Aug 2020 03:05:44
User entered 'No (N)'	System	13 Aug 2020 03:05:44

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:05:29', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '43097d6b-73f5-4456-bd5c-5fb75bb170ed'	System	13 Aug 2020 03:05:44
User entered 'No (N)'	System	13 Aug 2020 03:05:44

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:05:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '43097d6b-73f5-4456-bd5c-5fb75bb170ed'	System	13 Aug 2020 03:05:44
User entered 'None (1)'	System	13 Aug 2020 03:05:44

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:05:41', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '43097d6b-73f5-4456-bd5c-5fb75bb170ed'	System	13 Aug 2020 03:05:44
User entered '12 Aug 2020 20:05'	System	13 Aug 2020 03:05:44

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 4'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:15:15', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6a2d8ba4-b721-40b0-ae88-3be14f40f319'	System	14 Aug 2020 03:15:43
User entered 'None (1)'	System	14 Aug 2020 03:15:43

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:15:20', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6a2d8ba4-b721-40b0-ae88-3be14f40f319'	System	14 Aug 2020 03:15:43
User entered 'No (N)'	System	14 Aug 2020 03:15:43

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:15:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6a2d8ba4-b721-40b0-ae88-3be14f40f319'	System	14 Aug 2020 03:15:43
User entered 'No (N)'	System	14 Aug 2020 03:15:43

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:15:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6a2d8ba4-b721-40b0-ae88-3be14f40f319'	System	14 Aug 2020 03:15:43
User entered 'None (1)'	System	14 Aug 2020 03:15:43

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:15:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6a2d8ba4-b721-40b0-ae88-3be14f40f319'	System	14 Aug 2020 03:15:43
User entered '13 Aug 2020 20:15'	System	14 Aug 2020 03:15:43

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 5'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:01', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3e9349be-5a8b-4ab1-aa84-0290ce000a6b'	System	15 Aug 2020 03:44:21
User entered 'None (1)'	System	15 Aug 2020 03:44:21

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:06', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3e9349be-5a8b-4ab1-aa84-0290ce000a6b'	System	15 Aug 2020 03:44:21
User entered 'No (N)'	System	15 Aug 2020 03:44:21

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:11', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3e9349be-5a8b-4ab1-aa84-0290ce000a6b'	System	15 Aug 2020 03:44:21
User entered 'No (N)'	System	15 Aug 2020 03:44:21

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:15', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3e9349be-5a8b-4ab1-aa84-0290ce000a6b'	System	15 Aug 2020 03:44:21
User entered 'None (1)'	System	15 Aug 2020 03:44:21

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:19', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3e9349be-5a8b-4ab1-aa84-0290ce000a6b'	System	15 Aug 2020 03:44:21
User entered '14 Aug 2020 20:44'	System	15 Aug 2020 03:44:21

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 6'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ed995bc6-860d-48a4-a27e-2ef3737c542e'	System	16 Aug 2020 04:06:57
User entered 'None (1)'	System	16 Aug 2020 04:06:57

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:42', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ed995bc6-860d-48a4-a27e-2ef3737c542e'	System	16 Aug 2020 04:06:57
User entered 'No (N)'	System	16 Aug 2020 04:06:57

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:46', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ed995bc6-860d-48a4-a27e-2ef3737c542e'	System	16 Aug 2020 04:06:57
User entered 'No (N)'	System	16 Aug 2020 04:06:57

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:50', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ed995bc6-860d-48a4-a27e-2ef3737c542e'	System	16 Aug 2020 04:06:57
User entered 'None (1)'	System	16 Aug 2020 04:06:57

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:53', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ed995bc6-860d-48a4-a27e-2ef3737c542e'	System	16 Aug 2020 04:06:57
User entered '15 Aug 2020 21:06'	System	16 Aug 2020 04:06:57

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 7'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '11c1fa6e-6481-4c0e-be4a-df302f366f77'	System	17 Aug 2020 06:06:56
User entered 'None (1)'	System	17 Aug 2020 06:06:56

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '11c1fa6e-6481-4c0e-be4a-df302f366f77'	System	17 Aug 2020 06:06:56
User entered 'No (N)'	System	17 Aug 2020 06:06:56

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:45', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '11c1fa6e-6481-4c0e-be4a-df302f366f77'	System	17 Aug 2020 06:06:56
User entered 'No (N)'	System	17 Aug 2020 06:06:56

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:50', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '11c1fa6e-6481-4c0e-be4a-df302f366f77'	System	17 Aug 2020 06:06:56
User entered 'None (1)'	System	17 Aug 2020 06:06:56

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:06:54', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '11c1fa6e-6481-4c0e-be4a-df302f366f77'	System	17 Aug 2020 06:06:56
User entered '16 Aug 2020 23:06'	System	17 Aug 2020 06:06:56

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:35:47', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered 'None (0)'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:35:56', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered 'None (0)'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:36:02', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered 'None (0)'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:36:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered 'None (0)'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:36:15', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered 'None (0)'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:36:20', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered 'None (0)'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:36:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered 'No (N)'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T13:36:35', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '8fde1e69-1aa1-4204-a56d-4fb4bc3d75ec'	System	10 Aug 2020 20:36:38
User entered '10 Aug 2020 13:36'	System	10 Aug 2020 20:36:38

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 13:18'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 15:48'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:34', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered 'None (0)'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered 'None (0)'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered 'None (0)'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:33:53', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered 'None (0)'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:34:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered 'None (0)'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:34:03', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered 'None (0)'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:34:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered 'No (N)'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-10T21:34:15', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2accc572-33f6-4775-a529-7be980b53ddc'	System	11 Aug 2020 04:34:18
User entered '10 Aug 2020 21:34'	System	11 Aug 2020 04:34:18

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '10 Aug 2020 16:43'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 2'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:32', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered 'None (0)'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:39', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered 'None (0)'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:45', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered 'None (0)'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:51', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered 'None (0)'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:43:54', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered 'None (0)'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:44:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered 'None (0)'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:44:06', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered 'No (N)'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-11T22:44:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c0e6a2b4-e9ff-4976-ad43-7c9b7661adec'	System	12 Aug 2020 05:44:12
User entered '11 Aug 2020 22:44'	System	12 Aug 2020 05:44:12

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 3'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:05:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered 'None (0)'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:05:56', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered 'None (0)'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:06:02', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered 'None (0)'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:06:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered 'None (0)'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:06:12', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered 'None (0)'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:06:31', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered 'None (0)'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:06:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered 'No (N)'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-12T20:06:39', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'aaf4520d-1e3a-4b6f-9aae-258a3dcc1207'	System	13 Aug 2020 03:06:42
User entered '12 Aug 2020 20:06'	System	13 Aug 2020 03:06:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 4'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:15:47', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered 'None (0)'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:16:06', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered 'No interference with activity (1)'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:16:19', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered 'None (0)'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:16:24', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered 'No interference with activity (1)'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:16:29', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered 'None (0)'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:16:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered 'None (0)'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:16:43', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered 'No (N)'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-13T20:16:48', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5bbccddf-acaf-420a-a404-35a28f5b0090'	System	14 Aug 2020 03:16:52
User entered '13 Aug 2020 20:16'	System	14 Aug 2020 03:16:52

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 5'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:32', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered 'None (0)'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered 'None (0)'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:42', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered 'None (0)'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:47', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered 'None (0)'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:50', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered 'None (0)'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:53', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered 'None (0)'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:44:58', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered 'No (N)'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-14T20:45:01', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd43cd367-2d85-485c-8be1-eb98c4802ddf'	System	15 Aug 2020 03:45:06
User entered '14 Aug 2020 20:45'	System	15 Aug 2020 03:45:06

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 6'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:06:58', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered 'None (0)'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:07:06', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered 'None (0)'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:07:09', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered 'None (0)'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:07:15', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered 'None (0)'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:07:19', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered 'None (0)'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:07:22', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered 'None (0)'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:07:27', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered 'No (N)'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-15T21:07:30', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '5d659286-3715-420e-92c4-571ffcb84b72'	System	16 Aug 2020 04:07:33
User entered '15 Aug 2020 21:07'	System	16 Aug 2020 04:07:33

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 7'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:01', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered 'None (0)'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered 'None (0)'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:14', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered 'None (0)'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:18', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered 'None (0)'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:21', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered 'None (0)'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:27', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered 'None (0)'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered 'No (N)'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-08-16T23:07:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '90ca3021-dc9e-4559-abe2-abea8849e23c'	System	17 Aug 2020 06:07:42
User entered '16 Aug 2020 23:07'	System	17 Aug 2020 06:07:42

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:28:35

US3462097

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:01
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:36
User entered 'Yes (Y)'		07 Sep 2020 21:41:27

US3462097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:01
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:36
User entered '18 Aug 2020'		07 Sep 2020 21:41:27

US3462097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:01
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:36
User entered 'Contact Made (CONTACT MADE)'		07 Sep 2020 21:41:27

US3462097

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:01
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:36
User entered empty.		07 Sep 2020 21:41:27

US3462097

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:01
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:41
User entered 'Yes (Y)'		07 Sep 2020 21:41:30

US3462097

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:01
User entered 'I'	System	07 Sep 2020 21:41:30

US3462097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:54
User entered 'Yes (Y)'		07 Sep 2020 21:41:40

US3462097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:54
User entered '24 Aug 2020'		07 Sep 2020 21:41:40

US3462097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:54
User entered 'Contact Made (CONTACT MADE)'		07 Sep 2020 21:41:40

US3462097

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:54
User entered empty.		07 Sep 2020 21:41:40

US3462097

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:59
User entered 'Yes (Y)'		07 Sep 2020 21:41:44

US3462097

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User entered 'I'	System	07 Sep 2020 21:41:44

US3462097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:15
User entered 'Yes (Y)'		07 Sep 2020 21:41:55

US3462097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:15
User entered '31 Aug 2020'		07 Sep 2020 21:41:55

US3462097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:15
User entered 'Contact Made (CONTACT MADE)'		07 Sep 2020 21:41:55

US3462097

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:15
User entered empty.		07 Sep 2020 21:41:55

US3462097

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:20
User entered 'Yes (Y)'		07 Sep 2020 21:41:59

US3462097

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User entered 'I'	System	07 Sep 2020 21:41:59

US3462097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:16:42
User entered 'Yes (Y)'		14 Sep 2020 19:50:15

US3462097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:16:42
User closed query 'Visit date is 10Sept2020 in source document. Please verify and update accordingly.' (Site from CRA).		16 Nov 2020 19:09:56
Query 'Visit date is 10Sept2020 in source document. Please verify and update accordingly.' answered with 'Incorrect. All source pages show 14Sep2020.' (Site from CRA).		23 Sep 2020 15:23:40
User opened query 'Visit date is 10Sept2020 in source document. Please verify and update accordingly.' (Site from CRA).		22 Sep 2020 23:04:08
User entered '14 Sep 2020'		14 Sep 2020 19:50:15

US3462097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[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 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:16:42
User entered 'Clinic (Clinic)'		14 Sep 2020 19:50:15

US3462097

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'VISIT2'	System	14 Sep 2020 19:50:15

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User accepted default value 'Pre-Dose (PREDOSE)'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered 'Yes (Y)'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
Query 'Visit date is 10Sept2020 in source document. Please verify and update accordingly.' canceled (Site from CRA).		22 Sep 2020 23:05:42
User opened query 'Visit date is 10Sept2020 in source document. Please verify and update accordingly.' (Site from CRA).		22 Sep 2020 23:05:24
User entered '14 Sep 2020'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '12:09'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered '14 Sep 2020 12:09'	System	14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '37.1' C		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered 'Other (Other)'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered 'tympanic'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '73'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'bpm'	System	14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '15'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'breaths/min'	System	14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '120'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'mmHg'	System	14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '69'		14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'mmHg'	System	14 Sep 2020 22:08:13

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User accepted default value 'Post-Dose (POSTDOSE)'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered 'Yes (Y)'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '14 Sep 2020'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '13:17'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered '14 Sep 2020 13:17'	System	14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '37.3' C		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered 'Other (Other)'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered 'tympanic'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '60'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'bpm'	System	14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '15'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'breaths/min'	System	14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '118'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'mmHg'	System	14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:16
User entered '79'		14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'mmHg'	System	14 Sep 2020 22:08:40

US3462097

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:28
User entered 'No (N)'		14 Sep 2020 22:10:12

US3462097

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:28
User entered empty.		14 Sep 2020 22:10:12

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:43
User entered 'Yes (Y)'		14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:43
User entered empty.		14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

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 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:43
User entered empty.		14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:43
User entered '14 Sep 2020'		14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:43
User entered '12:43'		14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered '14 Sep 2020 12:43'	System	14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:43
User entered 'Left Arm (LEFT ARM)'		14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
DataPoint Verified.		02 Dec 2020 23:17:43
User entered 'ONCE'	System	14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 19:50:29

US3462097

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:52
User entered 'Yes (Y)'		14 Sep 2020 22:10:25

US3462097

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:52
User entered '14 Sep 2020'		14 Sep 2020 22:10:25

US3462097

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:17:52
User entered '12:37'		14 Sep 2020 22:10:25

US3462097

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered '14 Sep 2020 12:37'	System	14 Sep 2020 22:10:25

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:39:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:02
User entered '14 Sep 2020'		14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:02
User entered 'Yes (Y)'		14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:02
User entered '12:33'		14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered '14 Sep 2020 12:33'	System	14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:02
User entered 'No (N)'		14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:02
User entered empty.		14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered empty.	System	14 Sep 2020 22:10:36

US3462097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:10
User entered 'Yes (Y)'		14 Sep 2020 22:10:46

US3462097

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'I'	System	14 Sep 2020 22:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:12:01', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'f808b227-2e84-4033-bd20-7bb00f45407d'	System	14 Sep 2020 20:12:41
User entered 'Yes (Y)'	System	14 Sep 2020 20:12:41

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:12:14', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'f808b227-2e84-4033-bd20-7bb00f45407d'	System	14 Sep 2020 20:12:41
User entered '99.1'	System	14 Sep 2020 20:12:41

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:12:21', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'f808b227-2e84-4033-bd20-7bb00f45407d'	System	14 Sep 2020 20:12:41
User entered 'No (N)'	System	14 Sep 2020 20:12:41

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:12:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'f808b227-2e84-4033-bd20-7bb00f45407d'	System	14 Sep 2020 20:12:41
User entered '14 Sep 2020 13:12'	System	14 Sep 2020 20:12:41

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 13:03'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 15:33'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:24:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '06e17f84-dfcd-4dd8-be36-a88519b15e7a'	System	15 Sep 2020 04:24:50
User entered 'Yes (Y)'	System	15 Sep 2020 04:24:50

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:24:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '06e17f84-dfcd-4dd8-be36-a88519b15e7a'	System	15 Sep 2020 04:24:50
User entered '98.0'	System	15 Sep 2020 04:24:50

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:24:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '06e17f84-dfcd-4dd8-be36-a88519b15e7a'	System	15 Sep 2020 04:24:50
User entered 'No (N)'	System	15 Sep 2020 04:24:50

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:24:46', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '06e17f84-dfcd-4dd8-be36-a88519b15e7a'	System	15 Sep 2020 04:24:50
User entered '14 Sep 2020 21:24'	System	15 Sep 2020 04:24:50

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 16:28'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 2'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:13:24', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a87a7944-c22f-4495-ae6b-bdd32195f83c'	System	16 Sep 2020 02:15:05
User entered 'Yes (Y)'	System	16 Sep 2020 02:15:05

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:14:12', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a87a7944-c22f-4495-ae6b-bdd32195f83c'	System	16 Sep 2020 02:15:05
User entered '100.8'	System	16 Sep 2020 02:15:05

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:14:19', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a87a7944-c22f-4495-ae6b-bdd32195f83c'	System	16 Sep 2020 02:15:05
User entered 'Yes (Y)'	System	16 Sep 2020 02:15:05

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Added to CM log.' (Site from System).		23 Oct 2020 11:22:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Sep 2020 02:15:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:14:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a87a7944-c22f-4495-ae6b-bdd32195f83c'	System	16 Sep 2020 02:15:05
User entered '1'	System	16 Sep 2020 02:15:05

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:14:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a87a7944-c22f-4495-ae6b-bdd32195f83c'	System	16 Sep 2020 02:15:05
User entered '0'	System	16 Sep 2020 02:15:05

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:15:01', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a87a7944-c22f-4495-ae6b-bdd32195f83c'	System	16 Sep 2020 02:15:05
User entered '15 Sep 2020 19:15'	System	16 Sep 2020 02:15:05

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 3'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:08:53', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9b120dbb-fe6f-4061-b207-b69b5b9d6be5'	System	17 Sep 2020 02:09:33
User entered 'Yes (Y)'	System	17 Sep 2020 02:09:33

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:18', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9b120dbb-fe6f-4061-b207-b69b5b9d6be5'	System	17 Sep 2020 02:09:33
User entered '97.8'	System	17 Sep 2020 02:09:33

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:23', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9b120dbb-fe6f-4061-b207-b69b5b9d6be5'	System	17 Sep 2020 02:09:33
User entered 'No (N)'	System	17 Sep 2020 02:09:33

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:30', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9b120dbb-fe6f-4061-b207-b69b5b9d6be5'	System	17 Sep 2020 02:09:33
User entered '16 Sep 2020 19:09'	System	17 Sep 2020 02:09:33

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 4'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:28:20', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6994bf3c-0d45-4669-b602-9195e0323358'	System	18 Sep 2020 03:29:00
User entered 'Yes (Y)'	System	18 Sep 2020 03:29:00

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:28:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6994bf3c-0d45-4669-b602-9195e0323358'	System	18 Sep 2020 03:29:00
User entered '98.5'	System	18 Sep 2020 03:29:00

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:28:32', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6994bf3c-0d45-4669-b602-9195e0323358'	System	18 Sep 2020 03:29:00
User entered 'Yes (Y)'	System	18 Sep 2020 03:29:00

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Added to CM log.' (Site from System).		23 Oct 2020 11:22:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	18 Sep 2020 03:29:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:28:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6994bf3c-0d45-4669-b602-9195e0323358'	System	18 Sep 2020 03:29:00
User entered '1'	System	18 Sep 2020 03:29:00

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:28:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6994bf3c-0d45-4669-b602-9195e0323358'	System	18 Sep 2020 03:29:00
User entered '0'	System	18 Sep 2020 03:29:00

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:28:56', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '6994bf3c-0d45-4669-b602-9195e0323358'	System	18 Sep 2020 03:29:00
User entered '17 Sep 2020 20:28'	System	18 Sep 2020 03:29:00

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 5'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:37:54', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b43f016-bebd-4464-a8c0-193bd5dc3b25'	System	19 Sep 2020 02:40:10
User entered 'Yes (Y)'	System	19 Sep 2020 02:40:10

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b43f016-bebd-4464-a8c0-193bd5dc3b25'	System	19 Sep 2020 02:40:10
User entered '98.3'	System	19 Sep 2020 02:40:10

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:05', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b43f016-bebd-4464-a8c0-193bd5dc3b25'	System	19 Sep 2020 02:40:10
User entered 'No (N)'	System	19 Sep 2020 02:40:10

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:12', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3b43f016-bebd-4464-a8c0-193bd5dc3b25'	System	19 Sep 2020 02:40:10
User entered '18 Sep 2020 19:38'	System	19 Sep 2020 02:40:10

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 6'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:02', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e01d6ad9-73c3-45cb-a674-6460f63c7b72'	System	20 Sep 2020 02:25:23
User entered 'Yes (Y)'	System	20 Sep 2020 02:25:23

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e01d6ad9-73c3-45cb-a674-6460f63c7b72'	System	20 Sep 2020 02:25:23
User entered '96.9'	System	20 Sep 2020 02:25:23

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:22', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e01d6ad9-73c3-45cb-a674-6460f63c7b72'	System	20 Sep 2020 02:25:23
User entered 'No (N)'	System	20 Sep 2020 02:25:23

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e01d6ad9-73c3-45cb-a674-6460f63c7b72'	System	20 Sep 2020 02:25:23
User entered '19 Sep 2020 19:24'	System	20 Sep 2020 02:25:23

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 7'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:10:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c6397d1f-d048-494c-a80d-7659c7307f15'	System	21 Sep 2020 02:10:59
User entered 'Yes (Y)'	System	21 Sep 2020 02:10:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:10:42', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c6397d1f-d048-494c-a80d-7659c7307f15'	System	21 Sep 2020 02:10:59
User entered '99.7'	System	21 Sep 2020 02:10:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:10:48', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c6397d1f-d048-494c-a80d-7659c7307f15'	System	21 Sep 2020 02:10:59
User entered 'No (N)'	System	21 Sep 2020 02:10:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:10:52', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c6397d1f-d048-494c-a80d-7659c7307f15'	System	21 Sep 2020 02:10:59
User entered '20 Sep 2020 19:10'	System	21 Sep 2020 02:10:59

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:12:46', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9f6d9ce5-8b93-4da4-8695-c5852ef1f86e'	System	14 Sep 2020 20:13:58
User entered 'None (1)'	System	14 Sep 2020 20:13:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:13:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9f6d9ce5-8b93-4da4-8695-c5852ef1f86e'	System	14 Sep 2020 20:13:58
User entered 'No (N)'	System	14 Sep 2020 20:13:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:13:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9f6d9ce5-8b93-4da4-8695-c5852ef1f86e'	System	14 Sep 2020 20:13:58
User entered 'No (N)'	System	14 Sep 2020 20:13:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:13:48', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9f6d9ce5-8b93-4da4-8695-c5852ef1f86e'	System	14 Sep 2020 20:13:58
User entered 'None (1)'	System	14 Sep 2020 20:13:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:13:56', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '9f6d9ce5-8b93-4da4-8695-c5852ef1f86e'	System	14 Sep 2020 20:13:58
User entered '14 Sep 2020 13:13'	System	14 Sep 2020 20:13:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 13:03'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 15:33'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:25:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd4ed8013-cde3-4b59-834f-d6f072a0accf'	System	15 Sep 2020 04:25:51
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 04:25:51

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:25:16', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd4ed8013-cde3-4b59-834f-d6f072a0accf'	System	15 Sep 2020 04:25:51
User entered 'No (N)'	System	15 Sep 2020 04:25:51

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:25:35', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd4ed8013-cde3-4b59-834f-d6f072a0accf'	System	15 Sep 2020 04:25:51
User entered 'No (N)'	System	15 Sep 2020 04:25:51

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:25:43', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd4ed8013-cde3-4b59-834f-d6f072a0accf'	System	15 Sep 2020 04:25:51
User entered 'None (1)'	System	15 Sep 2020 04:25:51

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:25:48', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd4ed8013-cde3-4b59-834f-d6f072a0accf'	System	15 Sep 2020 04:25:51
User entered '14 Sep 2020 21:25'	System	15 Sep 2020 04:25:51

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 16:28'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 2'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:15:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '05bfb1ee-ccb6-41fc-aae9-c8041eaf195c'	System	16 Sep 2020 02:16:39
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 02:16:39

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:15:58', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '05bfb1ee-ccb6-41fc-aae9-c8041eaf195c'	System	16 Sep 2020 02:16:39
User entered 'No (N)'	System	16 Sep 2020 02:16:39

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:16:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '05bfb1ee-ccb6-41fc-aae9-c8041eaf195c'	System	16 Sep 2020 02:16:39
User entered 'No (N)'	System	16 Sep 2020 02:16:39

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:16:22', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '05bfb1ee-ccb6-41fc-aae9-c8041eaf195c'	System	16 Sep 2020 02:16:39
User entered 'None (1)'	System	16 Sep 2020 02:16:39

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:16:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '05bfb1ee-ccb6-41fc-aae9-c8041eaf195c'	System	16 Sep 2020 02:16:39
User entered '15 Sep 2020 19:16'	System	16 Sep 2020 02:16:39

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 3'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ecbd6f1a-0166-4662-b212-9db0e1631343'	System	17 Sep 2020 02:09:58
User entered 'None (1)'	System	17 Sep 2020 02:09:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ecbd6f1a-0166-4662-b212-9db0e1631343'	System	17 Sep 2020 02:09:58
User entered 'No (N)'	System	17 Sep 2020 02:09:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:44', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ecbd6f1a-0166-4662-b212-9db0e1631343'	System	17 Sep 2020 02:09:58
User entered 'No (N)'	System	17 Sep 2020 02:09:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:52', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ecbd6f1a-0166-4662-b212-9db0e1631343'	System	17 Sep 2020 02:09:58
User entered 'None (1)'	System	17 Sep 2020 02:09:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:09:55', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ecbd6f1a-0166-4662-b212-9db0e1631343'	System	17 Sep 2020 02:09:58
User entered '16 Sep 2020 19:09'	System	17 Sep 2020 02:09:58

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 4'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:29:06', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e2cd595-4bb9-4cc6-8060-f7025a13575d'	System	18 Sep 2020 03:29:42
User entered 'None (1)'	System	18 Sep 2020 03:29:42

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:29:18', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e2cd595-4bb9-4cc6-8060-f7025a13575d'	System	18 Sep 2020 03:29:42
User entered 'No (N)'	System	18 Sep 2020 03:29:42

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:29:25', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e2cd595-4bb9-4cc6-8060-f7025a13575d'	System	18 Sep 2020 03:29:42
User entered 'No (N)'	System	18 Sep 2020 03:29:42

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:29:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e2cd595-4bb9-4cc6-8060-f7025a13575d'	System	18 Sep 2020 03:29:42
User entered 'None (1)'	System	18 Sep 2020 03:29:42

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:29:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1e2cd595-4bb9-4cc6-8060-f7025a13575d'	System	18 Sep 2020 03:29:42
User entered '17 Sep 2020 20:29'	System	18 Sep 2020 03:29:42

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 5'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:18', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'df8ab790-1ff5-41f7-8981-6dcc62946d88'	System	19 Sep 2020 02:40:19
User entered 'None (1)'	System	19 Sep 2020 02:40:19

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:23', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'df8ab790-1ff5-41f7-8981-6dcc62946d88'	System	19 Sep 2020 02:40:19
User entered 'No (N)'	System	19 Sep 2020 02:40:19

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'df8ab790-1ff5-41f7-8981-6dcc62946d88'	System	19 Sep 2020 02:40:19
User entered 'No (N)'	System	19 Sep 2020 02:40:19

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:33', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'df8ab790-1ff5-41f7-8981-6dcc62946d88'	System	19 Sep 2020 02:40:19
User entered 'None (1)'	System	19 Sep 2020 02:40:19

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'df8ab790-1ff5-41f7-8981-6dcc62946d88'	System	19 Sep 2020 02:40:19
User entered '18 Sep 2020 19:38'	System	19 Sep 2020 02:40:19

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 6'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:44', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '235e2005-fd87-4e56-8db1-c307965fd9df'	System	20 Sep 2020 02:25:25
User entered 'None (1)'	System	20 Sep 2020 02:25:25

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '235e2005-fd87-4e56-8db1-c307965fd9df'	System	20 Sep 2020 02:25:25
User entered 'No (N)'	System	20 Sep 2020 02:25:25

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:53', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '235e2005-fd87-4e56-8db1-c307965fd9df'	System	20 Sep 2020 02:25:25
User entered 'No (N)'	System	20 Sep 2020 02:25:25

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:24:59', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '235e2005-fd87-4e56-8db1-c307965fd9df'	System	20 Sep 2020 02:25:25
User entered 'None (1)'	System	20 Sep 2020 02:25:25

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:09', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '235e2005-fd87-4e56-8db1-c307965fd9df'	System	20 Sep 2020 02:25:25
User entered '19 Sep 2020 19:25'	System	20 Sep 2020 02:25:25

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 7'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:10:59', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'b9b04bc7-8005-4ec2-8e8c-9b8127c46f66'	System	21 Sep 2020 02:11:30
User entered 'None (1)'	System	21 Sep 2020 02:11:30

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:11:05', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'b9b04bc7-8005-4ec2-8e8c-9b8127c46f66'	System	21 Sep 2020 02:11:30
User entered 'No (N)'	System	21 Sep 2020 02:11:30

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:11:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'b9b04bc7-8005-4ec2-8e8c-9b8127c46f66'	System	21 Sep 2020 02:11:30
User entered 'No (N)'	System	21 Sep 2020 02:11:30

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:11:14', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'b9b04bc7-8005-4ec2-8e8c-9b8127c46f66'	System	21 Sep 2020 02:11:30
User entered 'None (1)'	System	21 Sep 2020 02:11:30

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:11:28', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'b9b04bc7-8005-4ec2-8e8c-9b8127c46f66'	System	21 Sep 2020 02:11:30
User entered '20 Sep 2020 19:11'	System	21 Sep 2020 02:11:30

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:04', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered 'None (0)'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered 'None (0)'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:17', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered 'None (0)'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:23', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered 'None (0)'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered 'None (0)'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:31', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered 'None (0)'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:38', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered 'No (N)'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T13:14:42', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '54b40761-8cd2-4b43-8695-7cce55cd9731'	System	14 Sep 2020 20:14:45
User entered '14 Sep 2020 13:14'	System	14 Sep 2020 20:14:45

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 13:03'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 15:33'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:25:54', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered 'None (0)'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:25:59', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered 'No interference with activity (1)'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:26:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered 'No interference with activity (1)'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:26:17', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered 'No interference with activity (1)'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:26:24', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered 'None (0)'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:27:48', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered 'No interference with activity (1)'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:27:54', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered 'No (N)'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-14T21:28:10', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd1c0d914-625b-4bcf-82d9-0892d895f33a'	System	15 Sep 2020 04:28:12
User entered '14 Sep 2020 21:28'	System	15 Sep 2020 04:28:12

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '14 Sep 2020 16:28'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 2'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:16:46', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered 'No interference with activity (1)'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:17:09', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered 'Some interference with activity (2)'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:17:24', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered 'Some interference with activity (2)'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:17:35', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered 'Some interference with activity (2)'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:17:44', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered 'None (0)'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:17:56', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered 'No interference with activity (1)'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:18:07', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered 'No (N)'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-15T19:18:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'fb3f3bcd-8fe2-4533-9d8c-66e925c3fcf5'	System	16 Sep 2020 02:18:33
User entered '15 Sep 2020 19:18'	System	16 Sep 2020 02:18:33

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 3'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:02', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered 'None (0)'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered 'None (0)'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:19', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered 'No interference with activity (1)'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered 'None (0)'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:32', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered 'None (0)'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered 'None (0)'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:41', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered 'No (N)'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-16T19:10:45', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'a41b8c11-1b00-491f-9e47-dc0160785851'	System	17 Sep 2020 02:10:46
User entered '16 Sep 2020 19:10'	System	17 Sep 2020 02:10:46

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 4'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:29:48', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:30:01', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:30:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:30:17', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:30:22', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered 'None (0)'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:30:27', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered 'None (0)'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:30:31', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered 'No (N)'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-17T20:30:35', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2e2c5e0c-d0a2-4755-970e-d2af5eb936a3'	System	18 Sep 2020 03:30:37
User entered '17 Sep 2020 20:30'	System	18 Sep 2020 03:30:37

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 5'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered 'None (0)'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:44', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered 'None (0)'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:50', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered 'None (0)'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:55', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered 'None (0)'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:38:59', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered 'None (0)'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:39:03', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered 'None (0)'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:39:06', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered 'No (N)'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-18T19:39:09', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '42e123e3-fdcb-42c4-b7e8-96c3fdae4faa'	System	19 Sep 2020 02:40:30
User entered '18 Sep 2020 19:39'	System	19 Sep 2020 02:40:30

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 6'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:14', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered 'None (0)'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:22', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered 'None (0)'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:29', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered 'None (0)'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:35', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered 'None (0)'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:39', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered 'None (0)'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:43', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered 'None (0)'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered 'No (N)'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-19T19:25:53', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '0c7b5e95-fa38-40ad-b853-cb8177e60b1c'	System	20 Sep 2020 02:25:57
User entered '19 Sep 2020 19:25'	System	20 Sep 2020 02:25:57

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	14 Sep 2020 19:50:29
User entered 'Day 7'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:11:34', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered 'None (0)'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:11:40', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered 'No interference with activity (1)'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:11:56', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered 'No interference with activity (1)'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:12:09', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered 'None (0)'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:12:15', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered 'None (0)'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:12:18', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered 'None (0)'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:12:23', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered 'No (N)'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-09-20T19:12:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c9d033c3-2722-4c6b-8849-408af40da748'	System	21 Sep 2020 02:12:32
User entered '20 Sep 2020 19:12'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 19:50:29

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	21 Sep 2020 02:12:32
User entered 'Day 8'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	21 Sep 2020 02:12:32
User entered 'Day 9'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	21 Sep 2020 02:12:32
User entered 'Day 8'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:39:04

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	21 Sep 2020 02:12:32
User entered 'Day 9'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:39:04

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	21 Sep 2020 02:12:32
User entered 'Day 8'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	21 Sep 2020 02:12:32
User entered 'Day 9'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:39:04

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 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 02:12:32

US3462097

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:39:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 02:12:32

US3462097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:27
User entered 'Yes (Y)'		23 Sep 2020 21:09:29

US3462097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:27
User entered '21 Sep 2020'		23 Sep 2020 21:09:29

US3462097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:27
User entered 'Contact Made (CONTACT MADE)'		23 Sep 2020 21:09:29

US3462097

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:27
User entered empty.		23 Sep 2020 21:09:29

US3462097

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:31
User entered 'Yes (Y)'		23 Sep 2020 21:09:34

US3462097

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'I'	System	23 Sep 2020 21:09:34

US3462097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:43
User entered 'Yes (Y)'		09 Oct 2020 16:55:08

US3462097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:43
User entered '28 Sep 2020'		09 Oct 2020 16:55:08

US3462097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:43
User entered 'Contact Made (CONTACT MADE)'		09 Oct 2020 16:55:08

US3462097

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:43
User entered empty.		09 Oct 2020 16:55:08

US3462097

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:18:48
User entered 'Yes (Y)'		09 Oct 2020 16:55:11

US3462097

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'I'	System	09 Oct 2020 16:55:11

US3462097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:19:02
User entered 'Yes (Y)'		09 Oct 2020 16:55:20

US3462097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:19:02
User entered '5 Oct 2020'		09 Oct 2020 16:55:20

US3462097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:19:02
User entered 'Contact Made (CONTACT MADE)'		09 Oct 2020 16:55:20

US3462097

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:19:02
User entered empty.		09 Oct 2020 16:55:20

US3462097

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:19:07
User entered 'Yes (Y)'		09 Oct 2020 16:55:23

US3462097

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'I'	System	09 Oct 2020 16:55:23

US3462097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:13
User entered 'Yes (Y)'		09 Oct 2020 16:55:32

US3462097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:13
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		29 Oct 2020 13:47:39
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'		09 Oct 2020 16:56:35
answered with 'Visit done on Day 60, which is within window for D57 -3/+7.' (Site from System).		
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Oct 2020 16:55:32
User entered '8 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:55:32

US3462097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[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 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:13
User entered 'Clinic (Clinic)'		09 Oct 2020 16:55:32

US3462097

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'VISIT3'	System	09 Oct 2020 16:55:32

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered 'No (N)'		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered empty.	System	09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered empty.	System	09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered empty.	System	09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered empty.	System	09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:24
User entered empty.		09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered empty.	System	09 Oct 2020 16:56:42

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49

US3462097

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49

US3462097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:28
User entered 'No (N)'		09 Oct 2020 16:56:45

US3462097

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:28
User entered empty.		09 Oct 2020 16:56:45

US3462097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:35
User entered 'Yes (Y)'		09 Oct 2020 16:56:54

US3462097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:35
User entered '8 Oct 2020'		09 Oct 2020 16:56:54

US3462097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:35
User entered '11:30'		09 Oct 2020 16:56:54

US3462097

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered '8 Oct 2020 11:30'	System	09 Oct 2020 16:56:54

US3462097

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:21:38
User entered 'Yes (Y)'		09 Oct 2020 16:56:57

US3462097

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'I'	System	09 Oct 2020 16:56:57

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 64'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-10-11T21:40:44', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ce14626d-5185-4b7d-bc93-148b52dbc9e4'	System	12 Oct 2020 04:41:39
User entered 'No (N)'	System	12 Oct 2020 04:41:39

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Have you been exposed to someone with 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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-10-11T21:41:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ce14626d-5185-4b7d-bc93-148b52dbc9e4'	System	12 Oct 2020 04:41:39
User entered 'No (N)'	System	12 Oct 2020 04:41:39

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-10-11T21:41:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ce14626d-5185-4b7d-bc93-148b52dbc9e4'	System	12 Oct 2020 04:41:39
User entered '11 Oct 2020 21:41:36'	System	12 Oct 2020 04:41:39

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 71'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-10-19T12:04:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '12623db1-ffff-496d-9781-af8070a002f5'	System	19 Oct 2020 19:04:51
User entered 'No (N)'	System	19 Oct 2020 19:04:51

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Have you been exposed to someone with 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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-10-19T12:04:35', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '12623db1-ffff-496d-9781-af8070a002f5'	System	19 Oct 2020 19:04:51
User entered 'No (N)'	System	19 Oct 2020 19:04:51

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-10-19T12:04:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '12623db1-ffff-496d-9781-af8070a002f5'	System	19 Oct 2020 19:04:51
User entered '19 Oct 2020 12:04:49'	System	19 Oct 2020 19:04:51

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 78'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:39:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Please 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 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Please 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 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:58:48
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 92'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-10T05:52:49', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '805d505b-70f7-4b96-be85-c5a5e9ee2d6d'	System	10 Nov 2020 13:53:20
User entered 'No (N)'	System	10 Nov 2020 13:53:20

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-10T05:53:01', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '805d505b-70f7-4b96-be85-c5a5e9ee2d6d'	System	10 Nov 2020 13:53:20
User entered 'No (N)'	System	10 Nov 2020 13:53:20

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-10T05:53:16', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '805d505b-70f7-4b96-be85-c5a5e9ee2d6d'	System	10 Nov 2020 13:53:20
User entered '10 Nov 2020 05:53:16'	System	10 Nov 2020 13:53:20

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered 'Day 99'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-15T07:12:23', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'bab523be-0b79-442e-b58d-393b6c5b04c6'	System	15 Nov 2020 15:12:53
User entered 'No (N)'	System	15 Nov 2020 15:12:53

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Have you been exposed to someone with 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 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-15T07:12:44', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'bab523be-0b79-442e-b58d-393b6c5b04c6'	System	15 Nov 2020 15:12:53
User entered 'No (N)'	System	15 Nov 2020 15:12:53

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-15T07:12:52', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'bab523be-0b79-442e-b58d-393b6c5b04c6'	System	15 Nov 2020 15:12:53
User entered '15 Nov 2020 07:12:52'	System	15 Nov 2020 15:12:53

US3462097

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 20:28:35

US3462097

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:09
Data entry locked.	System	10 Aug 2020 20:28:35
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 20:28:35

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2020-11-21T10:22:12', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e9afb4d4-9762-4103-a5f1-a2a6848c37fb'	System	21 Nov 2020 18:22:38
User entered 'No (N)'	System	21 Nov 2020 18:22:38

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2020-11-21T10:22:16', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e9afb4d4-9762-4103-a5f1-a2a6848c37fb'	System	21 Nov 2020 18:22:38
User entered 'No (N)'	System	21 Nov 2020 18:22:38

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-21T10:22:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e9afb4d4-9762-4103-a5f1-a2a6848c37fb'	System	21 Nov 2020 18:22:38
User entered '21 Nov 2020 10:22:26'	System	21 Nov 2020 18:22:38

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2020-11-29T20:57:45', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7d272f69-812f-4508-9460-8f25d0324951'	System	30 Nov 2020 04:58:04
User entered 'No (N)'	System	30 Nov 2020 04:58:04

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2020-11-29T20:57:54', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7d272f69-812f-4508-9460-8f25d0324951'	System	30 Nov 2020 04:58:04
User entered 'No (N)'	System	30 Nov 2020 04:58:04

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-11-29T20:58:03', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '7d272f69-812f-4508-9460-8f25d0324951'	System	30 Nov 2020 04:58:04
User entered '29 Nov 2020 20:58:03'	System	30 Nov 2020 04:58:04

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2020-12-02T08:42:02', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd29cf4bc-03b6-4f6c-85a3-852064544d96'	System	02 Dec 2020 16:42:16
User entered 'No (N)'	System	02 Dec 2020 16:42:16

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2020-12-02T08:42:08', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd29cf4bc-03b6-4f6c-85a3-852064544d96'	System	02 Dec 2020 16:42:16
User entered 'No (N)'	System	02 Dec 2020 16:42:16

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-12-02T08:42:15', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd29cf4bc-03b6-4f6c-85a3-852064544d96'	System	02 Dec 2020 16:42:16
User entered '02 Dec 2020 08:42:15'	System	02 Dec 2020 16:42:16

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2020-12-10T13:00:34', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e6ccb067-19fe-42ca-9991-6380ab56f609'	System	10 Dec 2020 21:00:50
User entered 'No (N)'	System	10 Dec 2020 21:00:50

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2020-12-10T13:00:42', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e6ccb067-19fe-42ca-9991-6380ab56f609'	System	10 Dec 2020 21:00:50
User entered 'No (N)'	System	10 Dec 2020 21:00:50

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-12-10T13:00:47', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e6ccb067-19fe-42ca-9991-6380ab56f609' User entered '10 Dec 2020 13:00:47'	System	10 Dec 2020 21:00:50
	System	10 Dec 2020 21:00:50

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2020-12-16T08:19:26', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2fcb44a6-697c-4288-966b-90459e34f4e0'	System	16 Dec 2020 16:19:50
User entered 'No (N)'	System	16 Dec 2020 16:19:50

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2020-12-16T08:19:37', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2fcb44a6-697c-4288-966b-90459e34f4e0'	System	16 Dec 2020 16:19:50
User entered 'No (N)'	System	16 Dec 2020 16:19:50

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-12-16T08:19:46', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2fcb44a6-697c-4288-966b-90459e34f4e0'	System	16 Dec 2020 16:19:50
User entered '16 Dec 2020 08:19:46'	System	16 Dec 2020 16:19:50

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2020-12-23T16:11:05', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e50b1ae3-18b1-4e11-93c4-6e3c7feadb18'	System	24 Dec 2020 00:11:59
User entered 'No (N)'	System	24 Dec 2020 00:11:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2020-12-23T16:11:16', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e50b1ae3-18b1-4e11-93c4-6e3c7feadb18'	System	24 Dec 2020 00:11:59
User entered 'No (N)'	System	24 Dec 2020 00:11:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-12-23T16:11:30', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e50b1ae3-18b1-4e11-93c4-6e3c7feadb18'	System	24 Dec 2020 00:11:59
User entered '23 Dec 2020 16:11:30'	System	24 Dec 2020 00:11:59

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2020-12-31T12:16:25', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e5a0bfa2-9951-457f-9671-bfe987e9c084'	System	31 Dec 2020 20:16:38
User entered 'No (N)'	System	31 Dec 2020 20:16:38

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2020-12-31T12:16:31', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e5a0bfa2-9951-457f-9671-bfe987e9c084'	System	31 Dec 2020 20:16:38
User entered 'No (N)'	System	31 Dec 2020 20:16:38

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2020-12-31T12:16:36', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e5a0bfa2-9951-457f-9671-bfe987e9c084'	System	31 Dec 2020 20:16:38
User entered '31 Dec 2020 12:16:36'	System	31 Dec 2020 20:16:38

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-02-03T06:28:35', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1aae3b99-6a11-4305-ac76-d8283a420aca'	System	03 Feb 2021 14:28:58
User entered 'No (N)'	System	03 Feb 2021 14:28:58

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-02-03T06:28:43', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1aae3b99-6a11-4305-ac76-d8283a420aca'	System	03 Feb 2021 14:28:58
User entered 'No (N)'	System	03 Feb 2021 14:28:58

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-02-03T06:28:55', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '1aae3b99-6a11-4305-ac76-d8283a420aca'	System	03 Feb 2021 14:28:58
User entered '03 Feb 2021 06:28:55'	System	03 Feb 2021 14:28:58

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-03-04T12:27:04-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c4a7632a-ec7c-4ce3-a497-906247aabf26'	System	04 Mar 2021 20:27:29
User entered 'No (N)'	System	04 Mar 2021 20:27:29

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-03-04T12:27:14-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c4a7632a-ec7c-4ce3-a497-906247aabf26'	System	04 Mar 2021 20:27:29
User entered 'No (N)'	System	04 Mar 2021 20:27:29

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-03-04T12:27:25-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'c4a7632a-ec7c-4ce3-a497-906247aabf26'	System	04 Mar 2021 20:27:29
User entered '04 Mar 2021 12:27:25'	System	04 Mar 2021 20:27:29

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-03-10T14:30:55-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ac90b434-9355-4518-90e7-cb6efd6f532e'	System	10 Mar 2021 22:31:20
User entered 'No (N)'	System	10 Mar 2021 22:31:20

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-03-10T14:31:04-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ac90b434-9355-4518-90e7-cb6efd6f532e'	System	10 Mar 2021 22:31:20
User entered 'No (N)'	System	10 Mar 2021 22:31:20

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-03-10T14:31:16-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'ac90b434-9355-4518-90e7-cb6efd6f532e' User entered '10 Mar 2021 14:31:16'	System	10 Mar 2021 22:31:20
	System	10 Mar 2021 22:31:20

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-03-18T17:14:05-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2b003c0f-a181-4bfb-b505-e578c71d42ea'	System	19 Mar 2021 00:15:23
User entered 'No (N)'	System	19 Mar 2021 00:15:23

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-03-18T17:15:01-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2b003c0f-a181-4bfb-b505-e578c71d42ea'	System	19 Mar 2021 00:15:23
User entered 'No (N)'	System	19 Mar 2021 00:15:23

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-03-18T17:15:20-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '2b003c0f-a181-4bfb-b505-e578c71d42ea'	System	19 Mar 2021 00:15:23
User entered '18 Mar 2021 17:15:20'	System	19 Mar 2021 00:15:23

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-03-25T09:13:56-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e1972423-18d8-4061-9550-4f0c86ea74cd'	System	28 Mar 2021 22:58:20
User entered 'No (N)'	System	28 Mar 2021 22:58:20

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-03-25T09:14:08-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e1972423-18d8-4061-9550-4f0c86ea74cd'	System	28 Mar 2021 22:58:20
User entered 'No (N)'	System	28 Mar 2021 22:58:20

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-03-25T09:14:20-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'e1972423-18d8-4061-9550-4f0c86ea74cd' User entered '25 Mar 2021 09:14:20'	System	28 Mar 2021 22:58:20
	System	28 Mar 2021 22:58:20

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-03-31T14:10:14-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'bf5eec1f-cdf3-41ed-9948-66f5eb9669f4'	System	31 Mar 2021 21:10:28
User entered 'No (N)'	System	31 Mar 2021 21:10:28

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-03-31T14:10:21-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'bf5eec1f-cdf3-41ed-9948-66f5eb9669f4'	System	31 Mar 2021 21:10:28
User entered 'No (N)'	System	31 Mar 2021 21:10:28

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-03-31T14:10:25-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'bf5eec1f-cdf3-41ed-9948-66f5eb9669f4'	System	31 Mar 2021 21:10:28
User entered '31 Mar 2021 14:10:25'	System	31 Mar 2021 21:10:28

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-04-11T20:56:18-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '18fc3f81-102e-4694-b528-73cc7ca922e0'	System	12 Apr 2021 03:56:34
User entered 'No (N)'	System	12 Apr 2021 03:56:34

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-04-11T20:56:23-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '18fc3f81-102e-4694-b528-73cc7ca922e0'	System	12 Apr 2021 03:56:34
User entered 'No (N)'	System	12 Apr 2021 03:56:34

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-04-11T20:56:27-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '18fc3f81-102e-4694-b528-73cc7ca922e0'	System	12 Apr 2021 03:56:34
User entered '11 Apr 2021 20:56:27'	System	12 Apr 2021 03:56:34

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-04-14T11:55:58-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd982edac-aae8-4a3b-95a6-2b29404271d1' User entered 'No (N)'	System	14 Apr 2021 18:56:12
	System	14 Apr 2021 18:56:12

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-04-14T11:56:04-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd982edac-aae8-4a3b-95a6-2b29404271d1'	System	14 Apr 2021 18:56:12
User entered 'No (N)'	System	14 Apr 2021 18:56:12

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-04-14T11:56:08-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'd982edac-aae8-4a3b-95a6-2b29404271d1'	System	14 Apr 2021 18:56:12
User entered '14 Apr 2021 11:56:08'	System	14 Apr 2021 18:56:12

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-04-22T11:47:18-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3c448979-7bcf-467b-9c39-4c6b29a22a29' User entered 'No (N)'	System	22 Apr 2021 18:47:41
	System	22 Apr 2021 18:47:41

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-04-22T11:47:22-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3c448979-7bcf-467b-9c39-4c6b29a22a29'	System	22 Apr 2021 18:47:41
User entered 'No (N)'	System	22 Apr 2021 18:47:41

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-04-22T11:47:36-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: '3c448979-7bcf-467b-9c39-4c6b29a22a29'	System	22 Apr 2021 18:47:41
User entered '22 Apr 2021 11:47:36'	System	22 Apr 2021 18:47:41

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[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 (857a663ea0d567e3)', Time: '2021-04-28T05:38:54-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'f8670e59-379c-479f-befe-2b05314d3407' User entered 'No (N)'	System	28 Apr 2021 23:47:10
	System	28 Apr 2021 23:47:10

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

Have you been exposed to someone with 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 (857a663ea0d567e3)', Time: '2021-04-28T05:39:07-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'f8670e59-379c-479f-befe-2b05314d3407'	System	28 Apr 2021 23:47:10
User entered 'No (N)'	System	28 Apr 2021 23:47:10

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-04-28T05:39:18-07:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'f8670e59-379c-479f-befe-2b05314d3407'	System	28 Apr 2021 23:47:10
User entered '28 Apr 2021 05:39:18'	System	28 Apr 2021 23:47:10

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 02:58:48

US3462097

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:48
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 02:58:48

US3462097

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:39:04

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-03-04T12:27:56-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'be840808-b19b-45e1-a000-8b2ba237020b'	System	04 Mar 2021 20:28:06
User entered 'No (N)'	System	04 Mar 2021 20:28:06

US3462097

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:39:04

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (857a663ea0d567e3)', Time: '2021-03-04T12:28:03-08:00', User OID: 'PatientReportedOutcome (US3462097)', ODM File OID: 'be840808-b19b-45e1-a000-8b2ba237020b'	System	04 Mar 2021 20:28:06
User entered '04 Mar 2021 12:28:03'	System	04 Mar 2021 20:28:06

US3462097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
DataPoint Verified.		20 Apr 2021 20:50:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Nov 2020 19:33:58

US3462097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
DataPoint Verified.		20 Apr 2021 20:50:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:51:22
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Call done on Day 85.' (Site from System).		08 Nov 2020 19:34:13
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Nov 2020 19:33:58
User entered '3 Nov 2020'	(b) (4), (b) (6)	08 Nov 2020 19:33:58

US3462097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
DataPoint Verified.		20 Apr 2021 20:50:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Nov 2020 19:33:58

US3462097

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
DataPoint Verified.		20 Apr 2021 20:50:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Nov 2020 19:33:58

US3462097

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
DataPoint Verified.		20 Apr 2021 20:50:59
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Nov 2020 19:34:19

US3462097

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:49
User entered 'I'	System	08 Nov 2020 19:34:19

US3462097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		19 Apr 2021 21:59:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:05:28

US3462097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		19 Apr 2021 21:59:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:05:28

US3462097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		19 Apr 2021 21:59:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:05:28

US3462097

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		19 Apr 2021 21:59:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:05:28

US3462097

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:51:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:05:32

US3462097

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
User entered 'I'	System	01 Jan 2021 01:05:32

US3462097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:52:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:16

US3462097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:52:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:53:29
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Date is correct as entered.' (Site from System).		17 Feb 2021 21:24:21
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	17 Feb 2021 21:24:16
User entered '8 Jan 2021'	(b) (4), (b) (6)	17 Feb 2021 21:24:16

US3462097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:52:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:16

US3462097

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:52:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:16

US3462097

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:25

US3462097

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
User entered 'I'	System	17 Feb 2021 21:24:25

US3462097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:53:07
DataPoint Un-verified.		01 Apr 2021 18:41:25
DataPoint Verified.		01 Apr 2021 17:56:18
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:34

US3462097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:53:07
DataPoint Un-verified.		01 Apr 2021 18:41:27
DataPoint Verified.		01 Apr 2021 17:56:18
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		19 Feb 2021 20:22:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as entered.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:40
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Feb 2021 21:24:34
User entered '4 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 21:24:34

US3462097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:53:07
DataPoint Un-verified.		01 Apr 2021 18:41:29
DataPoint Verified.		01 Apr 2021 17:56:18
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:34

US3462097

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:53:07
DataPoint Un-verified.		01 Apr 2021 18:41:32
DataPoint Verified.		01 Apr 2021 17:56:18
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:34

US3462097

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
DataPoint Verified.		20 Apr 2021 20:54:36
DataPoint Un-verified.		01 Apr 2021 18:41:40
DataPoint Verified.		01 Apr 2021 17:56:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:24:45

US3462097

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:16
User entered 'I'	System	17 Feb 2021 21:24:45

US3462097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:54:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:17

US3462097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:54:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:17

US3462097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[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 07:59:36
DataPoint Verified.		20 Apr 2021 20:54:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:17

US3462097

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered 'VISIT4'	System	16 Mar 2021 19:17:17

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered 'No (N)'		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered '16 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered '09:37' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered '16 Mar 2021 09:37'	System	01 Apr 2021 16:28:48
User entered empty.	System	01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered '97.7' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered 'Tympanic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered '57' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered 'bpm'	System	01 Apr 2021 16:28:48
User entered empty.	System	01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered 'breaths/min'	System	01 Apr 2021 16:28:48
User entered empty.	System	01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered '128' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered 'mmHg'	System	01 Apr 2021 16:28:48
User entered empty.	System	01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:57:54
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:42
User entered '94' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:28:48
User entered empty.		01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered 'mmHg'	System	01 Apr 2021 16:28:48
User entered empty.	System	01 Apr 2021 16:25:07

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36

US3462097

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36

US3462097

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:58:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:29

US3462097

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:58:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:29

US3462097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:58:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:18:58

US3462097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:58:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16MAR2021 is recorded under visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16MAR2021 is recorded under visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'labs were sent in, Per PPD Portal Labs were Received 19 March 2021 and Accession # 1F600062157' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 18:32:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16MAR2021 is recorded under visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).		26 Mar 2021 06:45:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:18:58

US3462097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:58:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered '10:00'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:18:58

US3462097

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered '16 Mar 2021 10:00'	System	16 Mar 2021 19:18:58

US3462097

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		20 Apr 2021 20:58:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:19:12

US3462097

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered '1'	System	16 Mar 2021 19:19:12

US3462097

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:05:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:32:50

US3462097

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:05:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '12 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 21:32:50

US3462097

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:05:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:32:50

US3462097

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 21:32:50

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '12 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 21:33:05

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 21:56:44
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:11:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:38:06

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:05

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 21:56:44
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:11:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:38:06

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:05

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:05

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 01:39:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 21:33:05

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 01:39:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 21:33:05

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:05

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered empty.	System	18 Jan 2021 21:33:05

US3462097

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:04

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered empty.	System	18 Jan 2021 21:33:05

US3462097

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:17

US3462097

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:17

US3462097

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '01:51'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:17

US3462097

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered '12 Jan 2021 01:51'	System	18 Jan 2021 21:33:17

US3462097

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:31

US3462097

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:31

US3462097

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 20:04:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '01:47'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:31

US3462097

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:04

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered '12 Jan 2021 01:47'	System	18 Jan 2021 21:33:31

US3462097

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:39:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:08:04
DataPoint Verified.		06 Apr 2021 22:09:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:33
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:20:22
User entered 'Yes (Y)' reason for change: New Information		16 Mar 2021 19:20:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:57:18

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:35
User entered 'USA-US093-2021-mRNA-1273-P301000008'	System	31 Mar 2021 15:13:44
User entered 'New'	(b) (4), (b) (6)	31 Mar 2021 15:13:44

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 18:06:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 18:06:03
Data point term sent to Coder	System	30 Mar 2021 18:04:49
User entered 'PROSTATE CANCER'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 16:08:24
DataPoint Verified.	(b) (4)	19 Apr 2021 22:02:41
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 19:17:18
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Yes, not detected as of 1/12/21' (Site from Safety).		13 Apr 2021 18:01:12
User entered 'No (N)' reason for change: Per Query Resolution		13 Apr 2021 18:00:46
DataPoint Un-verified.		13 Apr 2021 18:00:19
Signature has been broken.		13 Apr 2021 18:00:19
User entered 'Yes (Y)' reason for change: Per Query Resolution		13 Apr 2021 18:00:19
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		09 Apr 2021 04:27:13
DataPoint Verified.		06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Mar 2021 18:04:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 18:04:09
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	30 Mar 2021 18:04:09
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '28 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:06:07
User entered '20 Feb 2021'		30 Mar 2021 18:03:51

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:39:51
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).		22 Apr 2021 13:27:00
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'Per PI subject has just been diagnosed and no treatment has been confirmed yet and since this is still an ongoing AE and was only diagnosed a little less then 2 months ago we can not provide a end date or stabilized date yet.' (Site from Safety).		21 Apr 2021 16:46:16
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).		09 Apr 2021 04:28:03
DataPoint Verified.		06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query '. PV Query: Please provide the event end date when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:29:03
User opened query '. PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).		23 Apr 2021 13:11:56
User entered empty.	System	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	30 Mar 2021 18:05:28
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '1' reason for change: Per Query Resolution	(b) (4)	30 Mar 2021 18:05:28
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
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	30 Mar 2021 18:05:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	30 Mar 2021 18:05:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
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	30 Mar 2021 18:05:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	30 Mar 2021 18:05:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 16:08:24
DataPoint Verified.	(b) (4)	19 Apr 2021 22:03:02
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 14-Sep-2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 19:17:21
Query 'PV Query: As the last dose of mRNA-1273 was given on 14-Sep-2020, please update the action taken with mRNA-1273 from none to not applicable.' answered with 'Updated Data' (Site from Safety).		12 Apr 2021 18:36:12
DataPoint Un-verified.		12 Apr 2021 18:35:43
Signature has been broken.		12 Apr 2021 18:35:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		12 Apr 2021 18:35:43
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 14-Sep-2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).		09 Apr 2021 04:25:39
DataPoint Verified.		06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Mar 2021 18:05:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 18:05:28
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:05:28
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 18:03:51
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 19:33:56
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 19:33:56
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 19:33:56
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). User closed query 'Per DM CLR: Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	System	23 Apr 2021 19:33:20
Query 'Per DM CLR: Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.' answered with 'Per PI subject has just been diagnosed and no treatment has been confirmed yet and since this is still an ongoing AE and was only diagnosed a little less then 2 months ago we can not provide a end date or treatment as subject has not yet been treated ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:49:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:49:31
User opened query 'Per DM CLR: Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	(b) (4), (b) (6)	03 Apr 2021 14:50:08
User entered '1'	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 19:33:20
Signature has been broken.		23 Apr 2021 19:33:20
User entered '1' reason for change: Data Entry Error		23 Apr 2021 19:33:20
DataPoint Verified.		06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 19:22:12
Signature has been broken.		23 Apr 2021 19:22:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error		23 Apr 2021 19:22:12
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).		23 Apr 2021 13:13:14
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 16:08:24
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 13:27:10
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).		22 Apr 2021 13:27:07
DataPoint Verified.		21 Apr 2021 20:03:24
DataPoint Un-verified.		21 Apr 2021 16:54:47
Signature has been broken.		21 Apr 2021 16:54:47
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error		21 Apr 2021 16:54:47

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Per PI subject has just been diagnosed and no treatment has been confirmed yet and since this is still an ongoing AE and was only diagnosed a little less than 2 months ago we can not provide a end date or treatment as subject has not yet been treated ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:52:55
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Per PI subject has just been diagnosed and no treatment has been confirmed yet and since this is still an ongoing AE and was only diagnosed a little less than 2 months ago we can not provide a end date or treatment as subject has not yet been treated ' (Site from Safety).		21 Apr 2021 16:52:22
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		09 Apr 2021 04:29:07
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. (Site from Safety).		09 Apr 2021 04:28:49
DataPoint Verified.		06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:03:51

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:43
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:42:01
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		26 Apr 2021 14:22:01
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Pt reports radiation beam therapy to begin 07MAY2021. More information to come.' (Site from Safety).		23 Apr 2021 19:32:49
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		23 Apr 2021 13:12:45
User opened query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		23 Apr 2021 13:12:06

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:11:40
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results. ' canceled (Site from Safety).		23 Apr 2021 13:11:34
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results. ' (Site from Safety).		23 Apr 2021 13:11:30
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 16:08:24
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:27:17
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		22 Apr 2021 13:27:14
DataPoint Verified.		21 Apr 2021 20:03:43
DataPoint Un-verified.		21 Apr 2021 16:54:47
Signature has been broken.		21 Apr 2021 16:54:47

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT CAME IN FOR D209. REPORTED DIAGNOSIS OF PROSTATE CANCER, RECORDED DIAGNOSIS AS AE, PE DONE AND VITALS CHECKED, will update when we have more information due to it only been less then 2 months subject has no treatment plan yet.'	(b) (4), (b) (6)	21 Apr 2021 16:54:47
reason for change: Data Entry Error Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Per PI subject has just been diagnosed and no treatment has been confirmed yet and since this is still an ongoing AE and was only diagnosed a little less then 2 months ago we can not provide a end date or treatment as subject has not yet been treated ' (Site from Safety).		21 Apr 2021 16:53:49
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Per PI subject has just been diagnosed and no treatment has been confirmed yet and since this is still an ongoing AE and was only diagnosed a little less then 2 months ago we can not provide a end date or treatment as subject has not yet been treated ' (Site from Safety).		21 Apr 2021 16:53:22
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		09 Apr 2021 04:29:26

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 04:28:28
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:35
User entered 'PATIENT CAME IN FOR D209. REPORTED DIAGNOSIS OF PROSTATE CANCER, RECORDED DIAGNOSIS AS AE, PE DONE AND VITALS CHECKED'	(b) (4), (b) (6)	30 Mar 2021 18:03:51

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:03:51

US3462097

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:03:51

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:39:04

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:08:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:11:28
User entered 'Yes (Y)'		08 Oct 2020 22:13:24

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:23:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:23:52
Data point term sent to Coder	System	09 Oct 2020 16:18:40
User entered 'albuterol'	(b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'asthma'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '180'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:18:20

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:25:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Oct 2020 16:25:29
Data point term sent to Coder	System	09 Oct 2020 16:19:42
User entered 'symbicort 160/4.5'	(b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'asthma'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'un Feb 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 16:18:54

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:26:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:26:00
Data point term sent to Coder	System	09 Oct 2020 16:19:42
User entered 'ibuprofen'	(b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'occasional headaches'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '400'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:19:38

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:30:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:30:06
Data point term sent to Coder	System	09 Oct 2020 16:29:02
User entered 'tylenol'	(b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'occasional headaches'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '325'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:28:23

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:39
Data point term sent to Coder	System	09 Oct 2020 16:35:18
User entered 'ibuprofen'	(b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the POST-DOSE FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST-DOSE FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 05:26:58
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the POST-DOSE FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST-DOSE FEVER did not meet the AE reporting criteria. ' answered with 'Solicited AE did not meet AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 05:48:30

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '400'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
User entered '1'	System	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
User entered '1'	System	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:52
User entered '804 (804)'	System	09 Oct 2020 16:34:27

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:40
Data point term sent to Coder	System	09 Oct 2020 16:35:22
User entered 'ibuprofen'	(b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the POST-DOSE MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST-DOSE MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 05:27:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the POST-DOSE MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST-DOSE MUSCLE ACHES did not meet the AE reporting criteria. ' answered with 'Solicited AE did not meet reporting criteria.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 05:48:59

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the POST-DOSE MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST-DOSE MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM). User entered 'post-dose muscle aches'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 02:47:14
	(b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '400'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
DataPoint Verified.		06 Apr 2021 22:11:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
User entered '1'	System	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
User entered '1'	System	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:56
User entered '804 (804)'	System	09 Oct 2020 16:34:58

US3462097

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:39:04

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:11:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:42:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:57:12

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'USA-US093-2021-MRNA-1273-P301000008'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Gregg'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Lucksinger'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '1900 Cypress Creek Rd'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Cedar Park'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'TX'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '78613'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:17:34
DataPoint Verified.		06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
User entered 'US'	(b) (4) System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 14:22:24
User entered '3'	System	22 Apr 2021 13:27:37
User entered '2'	System	13 Apr 2021 19:17:46
User entered '1'	System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'USA-US093-2021-MRNA-1273-P301000008'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Gregg'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Lucksinger'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '1900 Cypress Creek Rd'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Cedar Park'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'TX'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '78613'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:17:34
DataPoint Verified.		06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
User entered 'US'	(b) (4) System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 14:22:24
User entered '3'	System	22 Apr 2021 13:27:37
User entered '2'	System	13 Apr 2021 19:17:46
User entered '1'	System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:39:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
User entered '31/Mar/2021 11:18'	(b) (4) System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:39:04

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)	13 Apr 2021 19:17:34
DataPoint Verified.		06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'USA-US093-2021-MRNA-1273-P301000008'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Gregg'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Lucksinger'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '1900 Cypress Creek Rd'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Cedar Park'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'TX'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '78613'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:17:34
DataPoint Verified.		06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
User entered 'US'	(b) (4) System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 14:22:24
User entered '3'	System	22 Apr 2021 13:27:37
User entered '2'	System	13 Apr 2021 19:17:46
User entered '1'	System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:39:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:59:37
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 19:22:18
User entered '13/Apr/2021 15:17'	(b) (4) System	13 Apr 2021 19:17:46

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:39:04

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)	22 Apr 2021 13:27:28
DataPoint Verified.		20 Apr 2021 20:59:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 19:22:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:17:46

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'USA-US093-2021-MRNA-1273-P301000008'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Gregg'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Lucksinger'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '1900 Cypress Creek Rd'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Cedar Park'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'TX'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '78613'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:17:34
DataPoint Verified.		06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
User entered 'US'	(b) (4) System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 14:22:24
User entered '3'	System	22 Apr 2021 13:27:37
User entered '2'	System	13 Apr 2021 19:17:46
User entered '1'	System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:39:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:43:53
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 16:08:24
User entered '22/Apr/2021 08:27'	(b) (4) System	22 Apr 2021 13:27:37

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:39:04

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:43:53
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 16:08:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:27:45
User entered 'I'		22 Apr 2021 13:27:37

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'USA-US093-2021-MRNA-1273-P301000008'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'No (N)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Yes (Y)'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Gregg'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Lucksinger'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '1900 Cypress Creek Rd'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'Cedar Park'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered 'TX'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:13
User entered '78613'	System	31 Mar 2021 15:13:44

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:17:34
DataPoint Verified.		06 Apr 2021 22:05:23
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:01
User entered 'US'	(b) (4) System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 14:22:24
User entered '3'	System	22 Apr 2021 13:27:37
User entered '2'	System	13 Apr 2021 19:17:46
User entered '1'	System	31 Mar 2021 15:18:04

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:39:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Apr 2021 22:31:43
User entered '26/Apr/2021 10:22'	(b) (4) System	26 Apr 2021 14:22:24

US3462097

Folder: SAE USA-US093-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:39:04

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)	26 Apr 2021 22:31:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:22:24