

US3592127 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:55:16

All time stamps listed in this document are displayed in GMT

US3592127

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

[Participant ID](#)

US3592127

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

US3592127

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:24:15

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	MYOPIA
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 (3)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	HYPEROPIA
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 (4)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	ACID REFLUX
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 (8)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	MENORRHAGIA
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 FEB 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	FEB 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	BILATERAL CARPAL TUNNEL
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN FEB 2019
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 FEB 2019
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	FEB 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	RIGHT CARPAL TUNNEL SURGERY
Start date (dd MMM yyyy)	UN AUG 2019
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 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Condition	BILATERAL FEET NEUROPATHY, IDIOPATHIC
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: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	17:06 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:06
Height (xxx.x)	178.0 cm
Weight (xxx.x)	105.2 kg
BMI (xxx.x)	33.20288 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Date of assessment (dd MMM yyyy) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN FEB 2019

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:24:15

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 143729

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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)	11 AUG 2020
Time of assessment (00:00-23:59)	17:06 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:06
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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)	11 AUG 2020
Time of assessment (00:00-23:59)	18:57 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 18:57
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 18:21 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 18:21

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) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	17:56 (24 HR)
Collection date and time (derived)	11 AUG 2020 17:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:45	11 AUG 2020 17:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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: 11 Aug 2021 22:55:16

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

98.3 °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

11 AUG 2020 19:00

PC Open Date & Time

11 AUG 2020 18:41

PC Close Date & Time

11 AUG 2020 21:11

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 AUG 2020 22:06

PC Close Date & Time

12 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

97.7 °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

12 AUG 2020 15:12

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

98.3 °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

14 AUG 2020 00:04

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

15 AUG 2020 11:40

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 20:46

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

16 AUG 2020 19:17

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:11

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 19:01

PC Open Date & Time

11 AUG 2020 18:41

PC Close Date & Time

11 AUG 2020 21:11

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 AUG 2020 22:06

PC Close Date & Time

12 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

12 AUG 2020 15:13

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

14 AUG 2020 00:05

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

15 AUG 2020 11:41

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

15 AUG 2020 20:47

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

16 AUG 2020 19:18

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

17 AUG 2020 20:12

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 19:03
PC Open Date & Time	11 AUG 2020 18:41
PC Close Date & Time	11 AUG 2020 21:11

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 AUG 2020 22:06

PC Close Date & Time

12 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

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EAB) (1725)

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 15:14
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

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 3389

EAB) (1725)

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 00:06
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

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EAB) (1725)

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 11:41
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:48
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

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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EAB) (1725)

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:18
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

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EAB) (1725)

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:13
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3592127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:23:18

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:23:18

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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 SEP 2020
Time of assessment (00:00-23:59)	16:24 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:24
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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 SEP 2020
Time of assessment (00:00-23:59)	17:55 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 17:55
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3592127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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 SEP 2020

What was the treatment time? (00:00-23:59) 17:24 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 17:24

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

US3592127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

16:54 (24 HR)

Collection date and time (derived)

10 SEP 2020 16:54

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:52	10 SEP 2020 16:52
Nasopharyngeal Swab 2	No		

US3592127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:56

PC Open Date & Time

10 SEP 2020 17:44

PC Close Date & Time

10 SEP 2020 20:14

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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 98.9 °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 SEP 2020 11:16
PC Open Date & Time	10 SEP 2020 21:09
PC Close Date & Time	11 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 00:08

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

98.0 °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

12 SEP 2020 16:56

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

98.1 °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

13 SEP 2020 22:15

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

98.7 °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

14 SEP 2020 12:05

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 06:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 17:56

PC Open Date & Time

10 SEP 2020 17:44

PC Close Date & Time

10 SEP 2020 20:14

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

11 SEP 2020 11:16

PC Open Date & Time

10 SEP 2020 21:09

PC Close Date & Time

11 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

12 SEP 2020 00:09

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 3
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	12 SEP 2020 16:56
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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 SEP 2020 22:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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 SEP 2020 12:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

16 SEP 2020 06:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE. Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/> No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm) Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/> No <input type="radio"/>
Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm) Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - UNDERARM GLAND SWELLING OR TENDERNESS. Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 17:57
PC Open Date & Time	10 SEP 2020 17:44
PC Close Date & Time	10 SEP 2020 20:14

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 11:16
PC Open Date & Time	10 SEP 2020 21:09
PC Close Date & Time	11 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

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 ☒

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 00:09
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 16:57
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:16
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:06
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 06:36
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

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
EAB) (1725)

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US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3592127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:23:18

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:23:18

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:52:09

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:52:09

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:24:14

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 16:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

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.

US3592127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	16:43 (24 HR)
Collection date and time (derived)	9 OCT 2020 16:43

US3592127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:24:15

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 00:01:42
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

18 OCT 2020 21:21:13

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 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 OCT 2020 02:56:13
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 NOV 2020 01:56:48
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 <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	15 NOV 2020 01:32:16
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

19 NOV 2020 04:08:28

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 15:31:12
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 DEC 2020 14:40:30
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 07:31:36
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

17 DEC 2020 02:53:43

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

24 DEC 2020 03:28:19

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 14:53:04

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 13:50:40
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 14:22:30

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 15:07:05

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 06:04:52

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 09:43:14
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 05:29:59

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 05:42:57
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 08:32:22

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 07:15:32

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 00:01:26
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 00:01:27

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 00:15:23
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 APR 2021 12:03:16
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 APR 2021 07:34:42
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 APR 2021 10:11:40
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 05:58:29

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 03:15:34
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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="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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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="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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

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02 AUG 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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05 AUG 2021 00:01

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09 AUG 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

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16 AUG 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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02 SEP 2021 00:01

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06 SEP 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 <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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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09 SEP 2021 00:01

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13 SEP 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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="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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 <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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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13 JAN 2022 00:01

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17 JAN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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20 JAN 2022 00:01

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24 JAN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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27 JAN 2022 00:01

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31 JAN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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10 FEB 2022 00:01

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14 FEB 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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21 FEB 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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°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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

10 MAR 2022 00:01

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14 MAR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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°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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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17 MAR 2022 00:01

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21 MAR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 ☐
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 ☐

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

14 APR 2022 00:01

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18 APR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 <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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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="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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

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29 AUG 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 <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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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 <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"/>

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3592127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:55:16

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		27 FEB 2021 21:54:24

US3592127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:46:55

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:46:55

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

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

Visit date (dd MMM yyyy)	25 FEB 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:13
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3592127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00-23:59)

11:36 (24 HR)

Collection date and time (derived)

25 FEB 2021 11:36

US3592127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Date of Contact	12 NOV 2020
Time of Contact	16:58
Date and Time of Contact (derived)	12 NOV 2020 16:58
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	11 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	12 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	13 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

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

Temperature	37.1 C
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	14 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	15 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	16 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

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

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

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

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

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Form: Symptom Log (6)

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Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	18 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

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

Temperature	98.3 F
-------------	--------

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

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

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

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

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Form: Symptom Log (8)

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Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	19 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

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

Temperature	96.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (9)

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Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	20 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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Form: Symptom Log (10)

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Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 07:28:48

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	22 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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

Temperature	98.1 F
-------------	--------

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

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

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

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

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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (13)

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Symptom Day

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

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Form: Symptom Log (13)

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Generated On: 11 Aug 2021 22:55:16

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

Date	23 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

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

Temperature	96.2 F
-------------	--------

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

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

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

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

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Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 07:28:48

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Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	24 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

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

Temperature	94.5 F
-------------	--------

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

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

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

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

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Form: Symptom Log (14)

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Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	25 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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

Temperature	97.0 F
-------------	--------

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

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

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

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

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Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	28 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

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

Temperature	97.4 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Symptom Day

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

Date	26 NOV 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Date of Visit	13 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	13 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 14 NOV 2020

End Date 14 NOV 2020

Oxygen Saturation 93 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
Day 5	Yes	17 NOV 2020
Day 7	Yes	19 NOV 2020
Day 9	Yes	21 NOV 2020
Day 14	Yes	26 NOV 2020
Day 21	Yes	3 DEC 2020
Day 28	Yes	11 DEC 2020

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 10:35
Height (xxx.x)	178.0 cm
Weight (xxx.x)	101.9 kg
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

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Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 DEC 2020
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 13:39
Height (xxx.x)	178.0 cm
Weight (xxx.x)	102.1 kg
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 DEC 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: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 DEC 2020

US3592127

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

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

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

Folder OID	UNBLND_DECIDE
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US3592127

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

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

US3592127

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Height	
Weight	106.8 kg
BMI (xxx.x)	

US3592127

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Height	
Weight	106.8 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	13:33 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 13:33
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3592127

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Height	
Weight	106.8 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3592127

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3592127

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 14:13 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 14:13

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

US3592127

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

14 JAN 2021 13:40

US3592127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	13:44
Collection Date and Time (derived)	14 JAN 2021 13:44

US3592127

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3592127

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

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)	25 FEB 2021
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:13
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

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)	25 FEB 2021
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 12:29
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3592127

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3592127

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 11:57 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 11:57

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

US3592127

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592127

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592127

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

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	OLD57

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 13:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592127

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

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.

US3592127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 07:28:49

Generated On: 11 Aug 2021 22:55:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

13:21 (24 HR)

Collection date and time (derived)

16 MAR 2021 13:21

US3592127

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:49:01

Generated On: 11 Aug 2021 22:55:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

AEID	USA-US103-2020-MRNA-1273-P30 1000010
Adverse event	SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

AEID

Adverse event

LEFT KNEE PAIN POST
SURGICAL

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

AEID	
Adverse event	BUZZING IN RIGHT EAR
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

AEID	
Adverse event	VERTIGO
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)	27 MAR 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____ _____	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

AEID	
Adverse event	VOMITING
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)	27 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

AEID	
Adverse event	HYPERPARATHYROIDISM
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)	31 MAR 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

AEID	
Adverse event	HYPERCALCEMIA
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)	27 MAR 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 15:49:02

Generated On: 11 Aug 2021 22:55:16

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Name of Medication OZEMPIC

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

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) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Name of Medication EFFEXOR

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE
OSTEOARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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Name of Medication OSTEObIFLEX (BOSWELLIA,
VITAMIN C, MANGANESE,
VITAMIN D, GLUCOSAMINE,
CHONDROITIN,
METHYLSULFONYLMETHANE
(MSM), COLLAGEN SERRATA)

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE
OSTEOARTHRITIS

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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication PROTONIX (PANTOPRAZOLE)

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication OXYBUTININ

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication PROBIOTIC

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL SYNDROME

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 (12)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, COVID 19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication GLUCOSAMINE 1500MG,
VITAMIN C 60MG,
METHYLSULFONYLMETHANE
(MSM)/CHONDROITIN 1.1
G,MANGANESE 2 MG

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE
OSTEARTHRTIS

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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 1.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 07:28:47

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE PAIN POST
SURGICAL

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE PAIN POST
SURGICAL

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication VOMITING

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication MECLIZINE

Prophylaxis Yes ☐
No ☒

Indication VERTIGO

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 07:28:47

Generated On: 11 Aug 2021 22:55:16

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 07:28:48

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 DEC 2020	TOTAL LEFT KNEE REPLACEMENT	Medical History	
27 MAR 2021	CT SCAN	Diagnostic	
31 MAR 2021	ULTRASOUND	Diagnostic	
02 APR 2021	CT SCAN	Diagnostic	
06 APR 2021	BONE DENSITY DEXA SCAN	Diagnostic	
15 APR 2021	MAGNETIC RESONANCE IMAGING (MRI)	Diagnostic	
14 APR 2021	POSITRON EMISSION TOMOGRAPHY (PET)	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:55:16

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

US3592127

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:16

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 ☐

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

SAEID	USA-US103-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

SAEID	USA-US103-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/NOV/2020 14:12
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

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

SAEID	USA-US103-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/NOV/2020 14:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

SAEID	USA-US103-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/DEC/2020 13:18
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

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 07:28:50

Generated On: 11 Aug 2021 22:55:16

SAEID	USA-US103-2020-MRNA-1273-P301000010
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/JAN/2021 08:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3592127 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592127

Form: Participant Creation

Generated On: 11 Aug 2021 22:55:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 19:09:59
User entered 'US3592127'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 22:09:19

US3592127

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 23:25:47

US3592127

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:39
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 22:09:20

US3592127

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 23:25:47

US3592127

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'SCRN'	System	11 Aug 2020 23:25:47

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 22:09:21

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '57'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'YEARS'	System	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '57'	System	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered 'Female (F)'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered 'l'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 23:26:03

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:38
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Aug 2020'	System	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2020'	System	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:38
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:38
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:38
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:38
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 23:26:13

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 22:09:20

US3592127

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'l'	System	11 Aug 2020 23:26:18

US3592127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 23:26:18

US3592127

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:55:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:45:07

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
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 allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:47:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:47:26
Data point term sent to Coder	System	14 Aug 2020 16:46:39
User entered 'Allergic Rhinitis'	(b) (4), (b) (6)	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2015'	System	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2015'	System	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:45:47

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:47:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:47:27
Data point term sent to Coder	System	14 Aug 2020 16:46:39
User entered 'Myopia'	(b) (4), (b) (6)	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2009'	(b) (4), (b) (6)	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2009'	System	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2009'	System	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:46:02

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:47:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:47:26
Data point term sent to Coder	System	14 Aug 2020 16:46:39
User entered 'Hyperopia'	(b) (4), (b) (6)	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2009'	(b) (4), (b) (6)	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2009'	System	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2009'	System	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:46:16

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:48:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:48:24
Data point term sent to Coder	System	14 Aug 2020 16:47:40
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2008'	(b) (4), (b) (6)	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2008'	System	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2008'	System	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:46:46

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:48:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:48:25
Data point term sent to Coder	System	14 Aug 2020 16:47:40
User entered 'Sleep Apnea'	(b) (4), (b) (6)	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2008'	(b) (4), (b) (6)	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2008'	System	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2008'	System	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:47:05

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:48:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:48:25
Data point term sent to Coder	System	14 Aug 2020 16:47:44
User entered 'Diabetes Mellitus Type II'	(b) (4), (b) (6)	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2013'	(b) (4), (b) (6)	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2013'	System	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2013'	System	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:47:34

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:49:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:49:18
Data point term sent to Coder	System	14 Aug 2020 16:48:45
User entered 'Acid Reflux'	(b) (4), (b) (6)	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2010'	(b) (4), (b) (6)	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2010'	System	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2010'	System	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:47:52

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:49:39
Data point term sent to Coder	System	14 Aug 2020 16:48:45
User entered 'Irritable Bowel Syndrome'	(b) (4), (b) (6)	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Dec 2018'	(b) (4), (b) (6)	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Dec 2018'	System	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2018'	System	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:48:14

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:49:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:49:17
Data point term sent to Coder	System	14 Aug 2020 16:48:46
User entered 'Menorrhagia'	(b) (4), (b) (6)	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2009'	(b) (4), (b) (6)	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 16:49:03
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 16:48:38
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Feb 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:49:03
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2009'	System	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2009'	System	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Feb 2019'	System	14 Aug 2020 16:49:03
User entered empty.	System	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2019'	System	14 Aug 2020 16:49:03
User entered empty.	System	14 Aug 2020 16:48:38

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:50:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:50:21
Data point term sent to Coder	System	14 Aug 2020 16:49:49
User entered 'Overactive Bladder'	(b) (4), (b) (6)	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN May 2019'	(b) (4), (b) (6)	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'May 2019'	System	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2019'	System	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:49:49

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:51:17
Data point term sent to Coder	System	14 Aug 2020 16:50:51
User entered 'Bilateral Knee Osteoarthritis'	(b) (4), (b) (6)	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2010'	(b) (4), (b) (6)	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2010'	System	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2010'	System	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:50:19

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Lumbar spinal stenosis, LLT: Spinal stenosis lumbar - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:51:17
Data point term sent to Coder	System	14 Aug 2020 16:50:52
User entered 'Spinal Stenosis Lumbar'	(b) (4), (b) (6)	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Apr 2020'	(b) (4), (b) (6)	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Apr 2020'	System	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2020'	System	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:50:44

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Iron and trace metal metabolism disorders, HLT: Iron deficiencies, PT: Iron deficiency, LLT: Iron deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:53:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:53:18
Data point term sent to Coder	System	14 Aug 2020 16:51:55
User entered 'Iron Deficiency'	(b) (4), (b) (6)	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Feb 2019'	(b) (4), (b) (6)	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Feb 2019'	System	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2019'	System	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:51:03

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:53:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:53:18
Data point term sent to Coder	System	14 Aug 2020 16:51:56
User entered 'Bilateral Carpal Tunnel'	(b) (4), (b) (6)	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2016'	(b) (4), (b) (6)	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Jun 2020'	(b) (4), (b) (6)	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2016'	System	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2016'	System	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jun 2020'	System	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2020'	System	14 Aug 2020 16:51:44

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:40
Data point term sent to Coder	System	14 Aug 2020 16:54:03
User entered 'Depression'	(b) (4), (b) (6)	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2005'	(b) (4), (b) (6)	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2005'	System	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2005'	System	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:53:29

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:22
Data point term sent to Coder	System	14 Aug 2020 16:54:05
User entered 'Anxiety'	(b) (4), (b) (6)	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2018'	System	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2018'	System	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	14 Aug 2020 16:53:45

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User closed 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).	(b) (4), (b) (6)	08 Oct 2020 06:11:37
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.' answered with 'see line #9 MENORRHAGIA' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:09:55
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).	(b) (4), (b) (6)	30 Sep 2020 19:36:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:23
Data point term sent to Coder	System	14 Aug 2020 16:55:07
User entered 'Hysterectomy'	(b) (4), (b) (6)	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Feb 2019'	(b) (4), (b) (6)	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Feb 2019'	(b) (4), (b) (6)	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Feb 2019'	System	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2019'	System	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Feb 2019'	System	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2019'	System	14 Aug 2020 16:54:22

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:56:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:56:26
Data point term sent to Coder	System	14 Aug 2020 16:55:09
User entered 'Right Carpal Tunnel Surgery'	(b) (4), (b) (6)	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Aug 2019'	(b) (4), (b) (6)	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Aug 2019'	(b) (4), (b) (6)	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Aug 2019'	System	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2019'	System	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Aug 2019'	System	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2019'	System	14 Aug 2020 16:55:02

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:57:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:57:17
Data point term sent to Coder	System	14 Aug 2020 16:56:12
User entered 'Left Carpal Tunnel Surgery'	(b) (4), (b) (6)	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Jun 2020'	(b) (4), (b) (6)	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'UN Jun 2020'	(b) (4), (b) (6)	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jun 2020'	System	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2020'	System	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jun 2020'	System	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2020'	System	14 Aug 2020 16:55:25

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:30:27
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:21:07
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:01:24
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 16:01:24
Data point term sent to Coder	System	19 Aug 2020 15:37:03
User entered 'Bilateral feet neuropathy, idiopathic'	(b) (4), (b) (6)	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'un UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:30
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'Jan 2012'	System	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '2012'	System	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered empty.	System	19 Aug 2020 15:36:09

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered '17:06'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered '11 Aug 2020 17:06'	System	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered '178.0' cm	(b) (4), (b) (6)	14 Aug 2020 17:01:28
DataPoint set to visible.	System	11 Aug 2020 23:26:18

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered '105.2' kg	(b) (4), (b) (6)	14 Aug 2020 17:01:28
DataPoint set to visible.	System	11 Aug 2020 23:26:18

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
Amendment Manager: User entered '33.20288'	System	16 Sep 2020 23:52:47
User entered '33.2'	System	14 Aug 2020 17:01:28
DataPoint set to visible.	System	11 Aug 2020 23:26:18

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'kg/m2'	System	14 Aug 2020 17:01:28
DataPoint set to visible.	System	11 Aug 2020 23:26:18

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 10:22:25
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 20:01:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:35
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 05:02:55
User closed query 'Temperature is not less than 38.0 C/100.4 F as required by protocol. Please confirm temperature is correct.' (Site from System).	System	14 Aug 2020 17:01:36
Query 'Temperature is not less than 38.0 C/100.4 F as required by protocol. Please confirm temperature is correct.' answered by data change (Site from System).	System	14 Aug 2020 17:01:36
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 17:01:36
User opened query 'Temperature is not less than 38.0 C/100.4 F as required by protocol. Please confirm temperature is correct.' (Site from System).	System	14 Aug 2020 17:01:28
User entered '98.2' C	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:35
User entered '63'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'bpm'	System	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:35
User entered '16'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'breaths/min'	System	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:35
User entered '132'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'mmHg'	System	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:35
User entered '77'	(b) (4), (b) (6)	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User entered 'mmHg'	System	14 Aug 2020 17:01:28

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49

US3592127

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49

US3592127

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:45:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:58:57

US3592127

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:49
User entered '11 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:45:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 20:01:10
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 16:58:57

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered 'UN Feb 2019'	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:16

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:45:55
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:59:33

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

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 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered 'l'	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:10
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:58:46

US3592127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3592127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:16
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3592127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3592127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'VISIT1'	System	14 Aug 2020 17:03:21

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 23:14:21

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:44:55
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:44:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 23:14:21
User entered '143729' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 23:14:21

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 23:14:21

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

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)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:03:35

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

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)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:03:35

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:03:35

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:03:35

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:03:35

US3592127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:16

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:46:55
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 19:46:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:11
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:39:52

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:24:39
User entered '178' cm	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:24:39
User entered '105.2' kg	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:24:39
User entered '178' cm	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:24:39
User entered '105.2' kg	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '17:06'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered '11 Aug 2020 17:06'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '98.2' F	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '63'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'bpm'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '16'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'breaths/min'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '132'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'mmHg'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '71'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'mmHg'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:24:39
User entered '178' cm	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:24:39
User entered '105.2' kg	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:44:51
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:03:49
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	14 Aug 2020 17:03:11
User entered '18:57'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered '11 Aug 2020 18:57'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '98.3' F	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '61'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'bpm'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '18'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'breaths/min'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User entered '122'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'mmHg'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:54
User closed query 'Per CDM: Please confirm, CS or NCS.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 09:51:03
Query 'Per CDM: Please confirm, CS or NCS.' answered with 'not clinically significant ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 22:54:06
User opened query 'Per CDM: Please confirm, CS or NCS.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:28:12
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 06:27:43
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Confirm correct as entered' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 16:53:06
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:52:47
User entered '54'	(b) (4), (b) (6)	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'mmHg'	System	14 Aug 2020 17:03:11

US3592127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:46:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:04:04

US3592127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:46:00
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:04:04

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

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)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:31
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:31
User entered '18:21'	(b) (4), (b) (6)	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered '11 Aug 2020 18:21'	System	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:31
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:49:31
User entered 'ONCE'	System	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 23:26:46

US3592127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:04:31

US3592127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:41
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:04:31

US3592127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:49:41
User entered '17:56'	(b) (4), (b) (6)	14 Aug 2020 17:04:31

US3592127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered '11 Aug 2020 17:56'	System	14 Aug 2020 17:04:31

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:50:44
User entered '11 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:50:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:18:32
User closed query 'Please confirm, inconsistent with source. Source reflects 1756.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 15:18:29
Query 'Please confirm, inconsistent with source. Source reflects 1756.' answered with 'immunogenicity was collected at 17:56 swab was collected at 17:45 ' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 22:14:42
DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 22:13:57
User entered '17:45' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:13:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:50:44
User opened query 'Please confirm, inconsistent with source. Source reflects 1756.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 16:50:42
User entered '17:46'	(b) (4), (b) (6)	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered '11 Aug 2020 17:45'	System	08 Dec 2020 22:13:57
User entered '11 Aug 2020 17:46'	System	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:50:44
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:50:44
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered empty.	System	14 Aug 2020 17:04:44

US3592127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:50:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:05:03

US3592127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	14 Aug 2020 17:05:03

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T18:59:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'd8d4c95f-b76e-4916-9962-74056b78ee43'	System	12 Aug 2020 00:00:12
User entered 'Yes (Y)'	System	12 Aug 2020 00:00:12

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T18:59:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'd8d4c95f-b76e-4916-9962-74056b78ee43' User entered '98.3'	System	12 Aug 2020 00:00:12
	System	12 Aug 2020 00:00:12

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T18:59:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'd8d4c95f-b76e-4916-9962-74056b78ee43'	System	12 Aug 2020 00:00:12
User entered 'No (N)'	System	12 Aug 2020 00:00:12

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:00:06', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'd8d4c95f-b76e-4916-9962-74056b78ee43'	System	12 Aug 2020 00:00:12
User entered '11 Aug 2020 19:00'	System	12 Aug 2020 00:00:12

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 18:41'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 21:11'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 22:06'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 2'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:10:37', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e978cc3a-8e1e-4484-9536-2e770ce04e25'	System	12 Aug 2020 20:12:53
User entered 'Yes (Y)'	System	12 Aug 2020 20:12:53

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:12:26', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e978cc3a-8e1e-4484-9536-2e770ce04e25' User entered '97.7'	System	12 Aug 2020 20:12:53
	System	12 Aug 2020 20:12:53

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:12:41', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e978cc3a-8e1e-4484-9536-2e770ce04e25'	System	12 Aug 2020 20:12:53
User entered 'No (N)'	System	12 Aug 2020 20:12:53

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:12:49', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e978cc3a-8e1e-4484-9536-2e770ce04e25'	System	12 Aug 2020 20:12:53
User entered '12 Aug 2020 15:12'	System	12 Aug 2020 20:12:53

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 3'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:03:37', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72ca4451-c164-4240-b8e3-0b88083573d6' User entered 'Yes (Y)'	System	14 Aug 2020 05:05:00
	System	14 Aug 2020 05:05:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:04:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72ca4451-c164-4240-b8e3-0b88083573d6' User entered '98.3'	System	14 Aug 2020 05:05:00
	System	14 Aug 2020 05:05:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:04:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72ca4451-c164-4240-b8e3-0b88083573d6'	System	14 Aug 2020 05:05:00
User entered 'No (N)'	System	14 Aug 2020 05:05:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:04:58', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72ca4451-c164-4240-b8e3-0b88083573d6'	System	14 Aug 2020 05:05:00
User entered '14 Aug 2020 00:04'	System	14 Aug 2020 05:05:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 4'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:39:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7e9e35b1-c8cd-422f-91b3-a4fafd739de9' User entered 'Yes (Y)'	System	15 Aug 2020 16:40:24
	System	15 Aug 2020 16:40:24

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:40:10', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7e9e35b1-c8cd-422f-91b3-a4fafd739de9' User entered '97.0'	System	15 Aug 2020 16:40:24
	System	15 Aug 2020 16:40:24

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:40:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7e9e35b1-c8cd-422f-91b3-a4fafd739de9'	System	15 Aug 2020 16:40:24
User entered 'No (N)'	System	15 Aug 2020 16:40:24

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:40:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7e9e35b1-c8cd-422f-91b3-a4fafd739de9'	System	15 Aug 2020 16:40:24
User entered '15 Aug 2020 11:40'	System	15 Aug 2020 16:40:24

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 5'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:46:27', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '1b50ccf3-cd16-413f-af1c-bb9556120afb' User entered 'Yes (Y)'	System	16 Aug 2020 01:47:00
	System	16 Aug 2020 01:47:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:46:50', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '1b50ccf3-cd16-413f-af1c-bb9556120afb' User entered '97.2'	System	16 Aug 2020 01:47:00
	System	16 Aug 2020 01:47:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:46:54', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '1b50ccf3-cd16-413f-af1c-bb9556120afb'	System	16 Aug 2020 01:47:00
User entered 'No (N)'	System	16 Aug 2020 01:47:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:46:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '1b50ccf3-cd16-413f-af1c-bb9556120afb' User entered '15 Aug 2020 20:46'	System	16 Aug 2020 01:47:00
	System	16 Aug 2020 01:47:00

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 6'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:16:50', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '539cb20a-3f84-4fa1-9356-bb689fb74d5e' User entered 'Yes (Y)'	System	17 Aug 2020 00:17:48
	System	17 Aug 2020 00:17:48

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:17:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '539cb20a-3f84-4fa1-9356-bb689fb74d5e' User entered '97.3'	System	17 Aug 2020 00:17:48
	System	17 Aug 2020 00:17:48

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:17:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '539cb20a-3f84-4fa1-9356-bb689fb74d5e'	System	17 Aug 2020 00:17:48
User entered 'No (N)'	System	17 Aug 2020 00:17:48

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:17:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '539cb20a-3f84-4fa1-9356-bb689fb74d5e' User entered '16 Aug 2020 19:17'	System	17 Aug 2020 00:17:48
	System	17 Aug 2020 00:17:48

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 7'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:10:57', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b6375ec7-d1bd-4c28-b2eb-78be11d8b755'	System	18 Aug 2020 01:11:49
User entered 'Yes (Y)'	System	18 Aug 2020 01:11:49

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:11:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b6375ec7-d1bd-4c28-b2eb-78be11d8b755' User entered '97.1'	System	18 Aug 2020 01:11:49
	System	18 Aug 2020 01:11:49

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:11:43', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b6375ec7-d1bd-4c28-b2eb-78be11d8b755'	System	18 Aug 2020 01:11:49
User entered 'No (N)'	System	18 Aug 2020 01:11:49

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:11:47', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b6375ec7-d1bd-4c28-b2eb-78be11d8b755'	System	18 Aug 2020 01:11:49
User entered '17 Aug 2020 20:11'	System	18 Aug 2020 01:11:49

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:01:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '86a7623b-fdce-4f87-972d-a121fce855ae' User entered 'None (1)'	System	12 Aug 2020 00:01:49
	System	12 Aug 2020 00:01:49

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:01:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '86a7623b-fdce-4f87-972d-a121fce855ae' User entered 'No (N)'	System	12 Aug 2020 00:01:49
	System	12 Aug 2020 00:01:49

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:00:50', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '86a7623b-fdce-4f87-972d-a121fce855ae' User entered 'No (N)'	System	12 Aug 2020 00:01:49
	System	12 Aug 2020 00:01:49

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:00:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '86a7623b-fdce-4f87-972d-a121fce855ae' User entered 'None (1)'	System	12 Aug 2020 00:01:49
	System	12 Aug 2020 00:01:49

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:01:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '86a7623b-fdce-4f87-972d-a121fce855ae' User entered '11 Aug 2020 19:01'	System	12 Aug 2020 00:01:49
	System	12 Aug 2020 00:01:49

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 18:41'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 21:11'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 22:06'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 2'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:13:04', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe72914-f484-4f96-8bb5-fd94abc6efb0'	System	12 Aug 2020 20:13:55
User entered 'None (1)'	System	12 Aug 2020 20:13:55

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:13:31', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe72914-f484-4f96-8bb5-fd94abc6efb0'	System	12 Aug 2020 20:13:55
User entered 'No (N)'	System	12 Aug 2020 20:13:55

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:13:35', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe72914-f484-4f96-8bb5-fd94abc6efb0'	System	12 Aug 2020 20:13:55
User entered 'No (N)'	System	12 Aug 2020 20:13:55

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:13:43', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe72914-f484-4f96-8bb5-fd94abc6efb0'	System	12 Aug 2020 20:13:55
User entered 'None (1)'	System	12 Aug 2020 20:13:55

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:13:52', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe72914-f484-4f96-8bb5-fd94abc6efb0'	System	12 Aug 2020 20:13:55
User entered '12 Aug 2020 15:13'	System	12 Aug 2020 20:13:55

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 3'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:07', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '797b1754-0680-4ccd-bff0-8ebb9b78dbd7'	System	14 Aug 2020 05:05:37
User entered 'None (1)'	System	14 Aug 2020 05:05:37

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:11', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '797b1754-0680-4ccd-bff0-8ebb9b78dbd7'	System	14 Aug 2020 05:05:37
User entered 'No (N)'	System	14 Aug 2020 05:05:37

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '797b1754-0680-4ccd-bff0-8ebb9b78dbd7'	System	14 Aug 2020 05:05:37
User entered 'No (N)'	System	14 Aug 2020 05:05:37

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:27', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '797b1754-0680-4ccd-bff0-8ebb9b78dbd7'	System	14 Aug 2020 05:05:37
User entered 'None (1)'	System	14 Aug 2020 05:05:37

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:34', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '797b1754-0680-4ccd-bff0-8ebb9b78dbd7'	System	14 Aug 2020 05:05:37
User entered '14 Aug 2020 00:05'	System	14 Aug 2020 05:05:37

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 4'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:40:51', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3ee587b4-049d-49b4-a463-fbf15fb3d27b'	System	15 Aug 2020 16:41:20
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 16:41:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:40:55', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3ee587b4-049d-49b4-a463-fbf15fb3d27b' User entered 'No (N)'	System	15 Aug 2020 16:41:20
	System	15 Aug 2020 16:41:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:40:58', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3ee587b4-049d-49b4-a463-fbf15fb3d27b' User entered 'No (N)'	System	15 Aug 2020 16:41:20
	System	15 Aug 2020 16:41:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:13', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3ee587b4-049d-49b4-a463-fbf15fb3d27b'	System	15 Aug 2020 16:41:20
User entered 'None (1)'	System	15 Aug 2020 16:41:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3ee587b4-049d-49b4-a463-fbf15fb3d27b' User entered '15 Aug 2020 11:41'	System	15 Aug 2020 16:41:20
	System	15 Aug 2020 16:41:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 5'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:47:11', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f6a4c412-fd3e-40f4-9640-2160b3b4d655'	System	16 Aug 2020 01:47:46
User entered 'None (1)'	System	16 Aug 2020 01:47:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:47:24', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f6a4c412-fd3e-40f4-9640-2160b3b4d655'	System	16 Aug 2020 01:47:46
User entered 'No (N)'	System	16 Aug 2020 01:47:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:47:29', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f6a4c412-fd3e-40f4-9640-2160b3b4d655'	System	16 Aug 2020 01:47:46
User entered 'No (N)'	System	16 Aug 2020 01:47:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:47:38', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f6a4c412-fd3e-40f4-9640-2160b3b4d655'	System	16 Aug 2020 01:47:46
User entered 'None (1)'	System	16 Aug 2020 01:47:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:47:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f6a4c412-fd3e-40f4-9640-2160b3b4d655'	System	16 Aug 2020 01:47:46
User entered '15 Aug 2020 20:47'	System	16 Aug 2020 01:47:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 6'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:17:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '340b542c-c83b-4d2c-9767-1b756adb0070'	System	17 Aug 2020 00:18:20
User entered 'None (1)'	System	17 Aug 2020 00:18:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:03', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '340b542c-c83b-4d2c-9767-1b756adb0070'	System	17 Aug 2020 00:18:20
User entered 'No (N)'	System	17 Aug 2020 00:18:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:06', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '340b542c-c83b-4d2c-9767-1b756adb0070'	System	17 Aug 2020 00:18:20
User entered 'No (N)'	System	17 Aug 2020 00:18:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:14', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '340b542c-c83b-4d2c-9767-1b756adb0070'	System	17 Aug 2020 00:18:20
User entered 'None (1)'	System	17 Aug 2020 00:18:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '340b542c-c83b-4d2c-9767-1b756adb0070'	System	17 Aug 2020 00:18:20
User entered '16 Aug 2020 19:18'	System	17 Aug 2020 00:18:20

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 7'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:11:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6bdc5d5f-70fc-4451-93e3-3cb713d98a2b' User entered 'None (1)'	System	18 Aug 2020 01:12:22
	System	18 Aug 2020 01:12:22

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:03', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6bdc5d5f-70fc-4451-93e3-3cb713d98a2b' User entered 'No (N)'	System	18 Aug 2020 01:12:22
	System	18 Aug 2020 01:12:22

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:06', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6bdc5d5f-70fc-4451-93e3-3cb713d98a2b' User entered 'No (N)'	System	18 Aug 2020 01:12:22
	System	18 Aug 2020 01:12:22

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:13', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6bdc5d5f-70fc-4451-93e3-3cb713d98a2b' User entered 'None (1)'	System	18 Aug 2020 01:12:22
	System	18 Aug 2020 01:12:22

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6bdc5d5f-70fc-4451-93e3-3cb713d98a2b' User entered '17 Aug 2020 20:12'	System	18 Aug 2020 01:12:22
	System	18 Aug 2020 01:12:22

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:03:06', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16' User entered 'None (0)'	System	12 Aug 2020 00:03:33
	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:03:01', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16' User entered 'None (0)'	System	12 Aug 2020 00:03:33
	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:02:09', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16' User entered 'None (0)'	System	12 Aug 2020 00:03:33
	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:02:13', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16' User entered 'None (0)'	System	12 Aug 2020 00:03:33
	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:02:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16' User entered 'None (0)'	System	12 Aug 2020 00:03:33
	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:02:23', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16' User entered 'None (0)'	System	12 Aug 2020 00:03:33
	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:02:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16'	System	12 Aug 2020 00:03:33
User entered 'No (N)'	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-11T19:03:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e10388c0-b67b-4947-a34f-0699616fba16' User entered '11 Aug 2020 19:03'	System	12 Aug 2020 00:03:33
	System	12 Aug 2020 00:03:33

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 18:41'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 21:11'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Aug 2020 22:06'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 2'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:04', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered 'None (0)'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:12', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered 'None (0)'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered 'None (0)'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:21', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered 'None (0)'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:24', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered 'None (0)'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:29', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered 'None (0)'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:39', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered 'No (N)'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-12T15:14:47', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fa30e478-63d5-4d71-9ef4-d623e88bb952'	System	12 Aug 2020 20:14:51
User entered '12 Aug 2020 15:14'	System	12 Aug 2020 20:14:51

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 3'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered 'None (0)'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered 'None (0)'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:51', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered 'None (0)'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:54', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered 'None (0)'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:56', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered 'None (0)'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:05:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered 'None (0)'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:06:03', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered 'No (N)'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-14T00:06:10', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f0232f40-754a-4098-9837-6c7c6820d3b0' User entered '14 Aug 2020 00:06'	System	14 Aug 2020 05:06:12
	System	14 Aug 2020 05:06:12

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 4'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:23', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395'	System	15 Aug 2020 16:41:53
User entered 'None (0)'	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395' User entered 'None (0)'	System	15 Aug 2020 16:41:53
	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:31', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395' User entered 'None (0)'	System	15 Aug 2020 16:41:53
	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:35', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395' User entered 'None (0)'	System	15 Aug 2020 16:41:53
	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:38', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395' User entered 'None (0)'	System	15 Aug 2020 16:41:53
	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:41', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395' User entered 'None (0)'	System	15 Aug 2020 16:41:53
	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395'	System	15 Aug 2020 16:41:53
User entered 'No (N)'	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T11:41:50', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e2ecaddc-842f-4156-a011-aeb9a05fe395' User entered '15 Aug 2020 11:41'	System	15 Aug 2020 16:41:53
	System	15 Aug 2020 16:41:53

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 5'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:47:51', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6' User entered 'None (0)'	System	16 Aug 2020 01:48:21
	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:47:57', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6' User entered 'None (0)'	System	16 Aug 2020 01:48:21
	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:48:01', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6' User entered 'None (0)'	System	16 Aug 2020 01:48:21
	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:48:04', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6' User entered 'None (0)'	System	16 Aug 2020 01:48:21
	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:48:07', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6' User entered 'None (0)'	System	16 Aug 2020 01:48:21
	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:48:09', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6' User entered 'None (0)'	System	16 Aug 2020 01:48:21
	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:48:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6' User entered 'No (N)'	System	16 Aug 2020 01:48:21
	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-15T20:48:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '698d8c47-6867-42f5-a3d9-d966baaa07c6'	System	16 Aug 2020 01:48:21
User entered '15 Aug 2020 20:48'	System	16 Aug 2020 01:48:21

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 6'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275' User entered 'None (0)'	System	17 Aug 2020 00:18:55
	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275' User entered 'None (0)'	System	17 Aug 2020 00:18:55
	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:31', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275' User entered 'None (0)'	System	17 Aug 2020 00:18:55
	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:34', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275' User entered 'None (0)'	System	17 Aug 2020 00:18:55
	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:36', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275' User entered 'None (0)'	System	17 Aug 2020 00:18:55
	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:39', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275' User entered 'None (0)'	System	17 Aug 2020 00:18:55
	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:44', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275'	System	17 Aug 2020 00:18:55
User entered 'No (N)'	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-16T19:18:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6847e426-ff1d-4aa9-8ca5-8a31678f5275'	System	17 Aug 2020 00:18:55
User entered '16 Aug 2020 19:18'	System	17 Aug 2020 00:18:55

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 7'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:27', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a' User entered 'None (0)'	System	18 Aug 2020 01:13:04
	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:32', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a' User entered 'None (0)'	System	18 Aug 2020 01:13:04
	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:36', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a' User entered 'None (0)'	System	18 Aug 2020 01:13:04
	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a' User entered 'None (0)'	System	18 Aug 2020 01:13:04
	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:44', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a' User entered 'None (0)'	System	18 Aug 2020 01:13:04
	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:47', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a'	System	18 Aug 2020 01:13:04
User entered 'None (0)'	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:12:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a'	System	18 Aug 2020 01:13:04
User entered 'No (N)'	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-08-17T20:13:00', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '5e27effa-e3ce-452b-99b1-a8d52451d73a'	System	18 Aug 2020 01:13:04
User entered '17 Aug 2020 20:13'	System	18 Aug 2020 01:13:04

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 23:26:46

US3592127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Aug 2020 14:44:21

US3592127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:26
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 10:21:38
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm visit is out of window protocol deviation completed ' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 20:28:53
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Aug 2020 14:44:21
User entered '22 Aug 2020'	(b) (4), (b) (6)	23 Aug 2020 14:44:21

US3592127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Aug 2020 14:44:21

US3592127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:26
User entered empty.	(b) (4), (b) (6)	23 Aug 2020 14:44:21

US3592127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Aug 2020 14:46:19

US3592127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	23 Aug 2020 14:46:19

US3592127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 18:43:46

US3592127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:51
User entered '26 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 18:43:46

US3592127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:51
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 18:55:44
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 18:53:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 18:43:46

US3592127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 18:55:44
User entered 'contact was attempted 3 times and the subject was sent an e-mail.' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 18:53:24
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:43:46

US3592127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 18:43:53

US3592127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	04 Sep 2020 18:43:53

US3592127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:52:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 18:45:12

US3592127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:52:33
User entered '1 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 18:45:12

US3592127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:52:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 18:45:12

US3592127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:52:33
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:45:12

US3592127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:52:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 18:45:48

US3592127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	04 Sep 2020 18:45:48

US3592127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:53:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 22:25:49

US3592127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:53:10
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 22:25:49

US3592127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:53:10
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 22:25:49

US3592127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'VISIT2'	System	10 Sep 2020 22:25:49

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '16:24'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered '10 Sep 2020 16:24'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '98.0' F	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '58'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'bpm'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'breaths/min'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '147'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'mmHg'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:19:17
User closed query 'Please confirm, inconsistent with source. Source reflects diastolic to be 73.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 15:19:14
Query 'Please confirm, inconsistent with source. Source reflects diastolic to be 73.' answered with 'corrected value ' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 16:36:35
DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 16:36:25
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 16:36:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:54:56
User opened query 'Please confirm, inconsistent with source. Source reflects diastolic to be 73.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 16:54:18
User entered '75'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'mmHg'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '17:55'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered '10 Sep 2020 17:55'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '98.5' F	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '56'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'bpm'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'breaths/min'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '132'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'mmHg'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:54:56
User entered '68'	(b) (4), (b) (6)	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'mmHg'	System	11 Sep 2020 14:40:45

US3592127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:41:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:01
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:41:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:20
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

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)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:20
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:20
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:20
User entered '17:24'	(b) (4), (b) (6)	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered '10 Sep 2020 17:24'	System	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:55:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:55:20
User entered 'ONCE'	System	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 22:26:05

US3592127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 17:06:25

US3592127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:18
User entered '10 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 17:06:25

US3592127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:18
User entered '16:54'	(b) (4), (b) (6)	12 Sep 2020 17:06:25

US3592127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered '10 Sep 2020 16:54'	System	12 Sep 2020 17:06:25

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:24
User entered '10 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:24
User entered '16:52'	(b) (4), (b) (6)	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered '10 Sep 2020 16:52'	System	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:24
User entered 'No (N)'	(b) (4), (b) (6)	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:24
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered empty.	System	12 Sep 2020 17:06:38

US3592127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:56:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:43:50

US3592127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'I'	System	11 Sep 2020 14:43:50

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:55:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e6f551b0-f445-42bd-aabe-37e602b1eda6' User entered 'Yes (Y)'	System	10 Sep 2020 22:56:13
	System	10 Sep 2020 22:56:13

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:01', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e6f551b0-f445-42bd-aabe-37e602b1eda6' User entered '98.5'	System	10 Sep 2020 22:56:13
	System	10 Sep 2020 22:56:13

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:06', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e6f551b0-f445-42bd-aabe-37e602b1eda6' User entered 'No (N)'	System	10 Sep 2020 22:56:13
	System	10 Sep 2020 22:56:13

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:11', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e6f551b0-f445-42bd-aabe-37e602b1eda6'	System	10 Sep 2020 22:56:13
User entered '10 Sep 2020 17:56'	System	10 Sep 2020 22:56:13

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 17:44'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 20:14'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:14:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e14bdc58-bb71-4497-85bd-9f611b726fd1'	System	11 Sep 2020 16:16:20
User entered 'Yes (Y)'	System	11 Sep 2020 16:16:20

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:08', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e14bdc58-bb71-4497-85bd-9f611b726fd1' User entered '98.9'	System	11 Sep 2020 16:16:20
	System	11 Sep 2020 16:16:20

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:11', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e14bdc58-bb71-4497-85bd-9f611b726fd1'	System	11 Sep 2020 16:16:20
User entered 'No (N)'	System	11 Sep 2020 16:16:20

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e14bdc58-bb71-4497-85bd-9f611b726fd1'	System	11 Sep 2020 16:16:20
User entered '11 Sep 2020 11:16'	System	11 Sep 2020 16:16:20

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 21:09'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 2'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:07:14', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fcae3e95-1315-4fb7-8ea1-97c9fd55f5b8'	System	12 Sep 2020 05:08:48
User entered 'Yes (Y)'	System	12 Sep 2020 05:08:48

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:08:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fcae3e95-1315-4fb7-8ea1-97c9fd55f5b8' User entered '98.6'	System	12 Sep 2020 05:08:48
	System	12 Sep 2020 05:08:48

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:08:39', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fcae3e95-1315-4fb7-8ea1-97c9fd55f5b8'	System	12 Sep 2020 05:08:48
User entered 'No (N)'	System	12 Sep 2020 05:08:48

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:08:44', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fcae3e95-1315-4fb7-8ea1-97c9fd55f5b8'	System	12 Sep 2020 05:08:48
User entered '12 Sep 2020 00:08'	System	12 Sep 2020 05:08:48

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 3'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:55:52', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '0a2fb499-24ba-4d6a-bbf1-dd8e6e2f626d' User entered 'Yes (Y)'	System	12 Sep 2020 21:56:10
	System	12 Sep 2020 21:56:10

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:01', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '0a2fb499-24ba-4d6a-bbf1-dd8e6e2f626d' User entered '98.0'	System	12 Sep 2020 21:56:10
	System	12 Sep 2020 21:56:10

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:05', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '0a2fb499-24ba-4d6a-bbf1-dd8e6e2f626d' User entered 'No (N)'	System	12 Sep 2020 21:56:10
	System	12 Sep 2020 21:56:10

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:09', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '0a2fb499-24ba-4d6a-bbf1-dd8e6e2f626d' User entered '12 Sep 2020 16:56'	System	12 Sep 2020 21:56:10
	System	12 Sep 2020 21:56:10

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 4'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:10', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '68d7ac6f-d00b-4f0a-9348-c634f15a1145'	System	14 Sep 2020 03:15:31
User entered 'Yes (Y)'	System	14 Sep 2020 03:15:31

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '68d7ac6f-d00b-4f0a-9348-c634f15a1145' User entered '98.1'	System	14 Sep 2020 03:15:31
	System	14 Sep 2020 03:15:31

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:20', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '68d7ac6f-d00b-4f0a-9348-c634f15a1145'	System	14 Sep 2020 03:15:31
User entered 'No (N)'	System	14 Sep 2020 03:15:31

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:29', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '68d7ac6f-d00b-4f0a-9348-c634f15a1145'	System	14 Sep 2020 03:15:31
User entered '13 Sep 2020 22:15'	System	14 Sep 2020 03:15:31

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 5'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dad9b2c4-865f-4ccb-b912-8a0f76a0ccd8' User entered 'Yes (Y)'	System	14 Sep 2020 17:06:03
	System	14 Sep 2020 17:06:03

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:36', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dad9b2c4-865f-4ccb-b912-8a0f76a0ccd8' User entered '98.7'	System	14 Sep 2020 17:06:03
	System	14 Sep 2020 17:06:03

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:42', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dad9b2c4-865f-4ccb-b912-8a0f76a0ccd8'	System	14 Sep 2020 17:06:03
User entered 'No (N)'	System	14 Sep 2020 17:06:03

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dad9b2c4-865f-4ccb-b912-8a0f76a0ccd8' User entered '14 Sep 2020 12:05'	System	14 Sep 2020 17:06:03
	System	14 Sep 2020 17:06:03

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 6'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:34:52', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '2601bc2f-1977-4d7c-a40a-4cb1cb670747' User entered 'Yes (Y)'	System	16 Sep 2020 11:35:15
	System	16 Sep 2020 11:35:15

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:03', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '2601bc2f-1977-4d7c-a40a-4cb1cb670747' User entered '98.3'	System	16 Sep 2020 11:35:15
	System	16 Sep 2020 11:35:15

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:09', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '2601bc2f-1977-4d7c-a40a-4cb1cb670747'	System	16 Sep 2020 11:35:15
User entered 'No (N)'	System	16 Sep 2020 11:35:15

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:12', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '2601bc2f-1977-4d7c-a40a-4cb1cb670747' User entered '16 Sep 2020 06:35'	System	16 Sep 2020 11:35:15
	System	16 Sep 2020 11:35:15

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 7'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:20', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '465a1a0e-2123-410c-952b-6861fbccc69b' User entered 'None (1)'	System	10 Sep 2020 22:56:48
	System	10 Sep 2020 22:56:48

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '465a1a0e-2123-410c-952b-6861fbccc69b' User entered 'No (N)'	System	10 Sep 2020 22:56:48
	System	10 Sep 2020 22:56:48

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:29', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '465a1a0e-2123-410c-952b-6861fbccc69b' User entered 'No (N)'	System	10 Sep 2020 22:56:48
	System	10 Sep 2020 22:56:48

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:37', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '465a1a0e-2123-410c-952b-6861fbccc69b' User entered 'None (1)'	System	10 Sep 2020 22:56:48
	System	10 Sep 2020 22:56:48

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:56:46', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '465a1a0e-2123-410c-952b-6861fbccc69b' User entered '10 Sep 2020 17:56'	System	10 Sep 2020 22:56:48
	System	10 Sep 2020 22:56:48

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 17:44'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 20:14'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:21', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f01e3493-75df-47db-a34e-d9c2eb1976c8'	System	11 Sep 2020 16:16:52
User entered 'None (1)'	System	11 Sep 2020 16:16:52

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f01e3493-75df-47db-a34e-d9c2eb1976c8' User entered 'No (N)'	System	11 Sep 2020 16:16:52
	System	11 Sep 2020 16:16:52

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:29', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f01e3493-75df-47db-a34e-d9c2eb1976c8' User entered 'No (N)'	System	11 Sep 2020 16:16:52
	System	11 Sep 2020 16:16:52

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:33', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f01e3493-75df-47db-a34e-d9c2eb1976c8'	System	11 Sep 2020 16:16:52
User entered 'None (1)'	System	11 Sep 2020 16:16:52

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:35', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f01e3493-75df-47db-a34e-d9c2eb1976c8'	System	11 Sep 2020 16:16:52
User entered '11 Sep 2020 11:16'	System	11 Sep 2020 16:16:52

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 21:09'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 2'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:08:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a468e1d8-7cf3-417c-8b73-2a22b5a23c71' User entered 'None (1)'	System	12 Sep 2020 05:09:24
	System	12 Sep 2020 05:09:24

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:04', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a468e1d8-7cf3-417c-8b73-2a22b5a23c71' User entered 'No (N)'	System	12 Sep 2020 05:09:24
	System	12 Sep 2020 05:09:24

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:09', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a468e1d8-7cf3-417c-8b73-2a22b5a23c71' User entered 'No (N)'	System	12 Sep 2020 05:09:24
	System	12 Sep 2020 05:09:24

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a468e1d8-7cf3-417c-8b73-2a22b5a23c71' User entered 'None (1)'	System	12 Sep 2020 05:09:24
	System	12 Sep 2020 05:09:24

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:21', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a468e1d8-7cf3-417c-8b73-2a22b5a23c71' User entered '12 Sep 2020 00:09'	System	12 Sep 2020 05:09:24
	System	12 Sep 2020 05:09:24

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 3'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:14', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87ce7d09-beb6-4526-9060-8e1e655ae849' User entered 'None (1)'	System	12 Sep 2020 21:56:41
	System	12 Sep 2020 21:56:41

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87ce7d09-beb6-4526-9060-8e1e655ae849' User entered 'No (N)'	System	12 Sep 2020 21:56:41
	System	12 Sep 2020 21:56:41

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87ce7d09-beb6-4526-9060-8e1e655ae849' User entered 'No (N)'	System	12 Sep 2020 21:56:41
	System	12 Sep 2020 21:56:41

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:33', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87ce7d09-beb6-4526-9060-8e1e655ae849' User entered 'None (1)'	System	12 Sep 2020 21:56:41
	System	12 Sep 2020 21:56:41

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:39', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87ce7d09-beb6-4526-9060-8e1e655ae849' User entered '12 Sep 2020 16:56'	System	12 Sep 2020 21:56:41
	System	12 Sep 2020 21:56:41

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 4'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:36', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a2d721e2-eaaa-4192-a3f5-26dc92049854' User entered 'None (1)'	System	14 Sep 2020 03:16:04
	System	14 Sep 2020 03:16:04

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a2d721e2-eaaa-4192-a3f5-26dc92049854' User entered 'No (N)'	System	14 Sep 2020 03:16:04
	System	14 Sep 2020 03:16:04

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:44', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a2d721e2-eaaa-4192-a3f5-26dc92049854' User entered 'No (N)'	System	14 Sep 2020 03:16:04
	System	14 Sep 2020 03:16:04

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:15:55', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a2d721e2-eaaa-4192-a3f5-26dc92049854' User entered 'None (1)'	System	14 Sep 2020 03:16:04
	System	14 Sep 2020 03:16:04

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:00', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a2d721e2-eaaa-4192-a3f5-26dc92049854' User entered '13 Sep 2020 22:16'	System	14 Sep 2020 03:16:04
	System	14 Sep 2020 03:16:04

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 5'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:49', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '895cef72-ab0d-4208-9030-89f73a944d11' User entered 'None (1)'	System	14 Sep 2020 17:06:12
	System	14 Sep 2020 17:06:12

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '895eef72-ab0d-4208-9030-89f73a944d11' User entered 'No (N)'	System	14 Sep 2020 17:06:12
	System	14 Sep 2020 17:06:12

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:56', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '895eef72-ab0d-4208-9030-89f73a944d11' User entered 'No (N)'	System	14 Sep 2020 17:06:12
	System	14 Sep 2020 17:06:12

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:05:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '895cef72-ab0d-4208-9030-89f73a944d11' User entered 'None (1)'	System	14 Sep 2020 17:06:12
	System	14 Sep 2020 17:06:12

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:03', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '895eef72-ab0d-4208-9030-89f73a944d11' User entered '14 Sep 2020 12:06'	System	14 Sep 2020 17:06:12
	System	14 Sep 2020 17:06:12

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 6'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:33', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be153523-166a-4aca-95bd-4f42b53d6e81' User entered 'None (1)'	System	16 Sep 2020 11:35:54
	System	16 Sep 2020 11:35:54

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:38', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be153523-166a-4aca-95bd-4f42b53d6e81' User entered 'No (N)'	System	16 Sep 2020 11:35:54
	System	16 Sep 2020 11:35:54

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:42', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be153523-166a-4aca-95bd-4f42b53d6e81' User entered 'No (N)'	System	16 Sep 2020 11:35:54
	System	16 Sep 2020 11:35:54

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:46', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be153523-166a-4aca-95bd-4f42b53d6e81' User entered 'None (1)'	System	16 Sep 2020 11:35:54
	System	16 Sep 2020 11:35:54

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:50', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be153523-166a-4aca-95bd-4f42b53d6e81' User entered '16 Sep 2020 06:35'	System	16 Sep 2020 11:35:54
	System	16 Sep 2020 11:35:54

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 7'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:10', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919' User entered 'None (0)'	System	10 Sep 2020 22:57:49
	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919' User entered 'None (0)'	System	10 Sep 2020 22:57:49
	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:19', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919' User entered 'None (0)'	System	10 Sep 2020 22:57:49
	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:27', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919' User entered 'None (0)'	System	10 Sep 2020 22:57:49
	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:31', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919' User entered 'None (0)'	System	10 Sep 2020 22:57:49
	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:34', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919' User entered 'None (0)'	System	10 Sep 2020 22:57:49
	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:44', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919' User entered 'No (N)'	System	10 Sep 2020 22:57:49
	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-10T17:57:47', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bb3fd293-e2d4-4597-beb7-f9cdaa9b1919'	System	10 Sep 2020 22:57:49
User entered '10 Sep 2020 17:57'	System	10 Sep 2020 22:57:49

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 17:44'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 20:14'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered 'None (0)'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:42', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered 'None (0)'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered 'None (0)'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered 'None (0)'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:50', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered 'None (0)'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:53', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered 'None (0)'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:57', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered 'No (N)'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-11T11:16:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e92b43dd-49b2-4de3-8faa-b654dc01342c' User entered '11 Sep 2020 11:16'	System	11 Sep 2020 16:17:12
	System	11 Sep 2020 16:17:12

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '10 Sep 2020 21:09'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 2'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:26', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered 'None (0)'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:29', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered 'None (0)'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:32', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered 'None (0)'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:35', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered 'None (0)'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:38', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered 'None (0)'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:41', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered 'None (0)'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered 'No (N)'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T00:09:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a677e6b3-e0d6-4e9c-89c7-9f3c5c5b895c' User entered '12 Sep 2020 00:09'	System	12 Sep 2020 05:09:52
	System	12 Sep 2020 05:09:52

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 3'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered 'None (0)'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered 'None (0)'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:51', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered 'None (0)'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:56:55', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered 'None (0)'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:57:04', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered 'None (0)'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:57:08', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered 'None (0)'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:57:13', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered 'No (N)'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-12T16:57:33', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'e3651b54-ff1d-44f5-a0fe-192f9e0b4594' User entered '12 Sep 2020 16:57'	System	12 Sep 2020 21:59:38
	System	12 Sep 2020 21:59:38

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 4'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:05', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered 'None (0)'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:07', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered 'None (0)'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:09', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered 'None (0)'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:12', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered 'None (0)'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:14', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered 'None (0)'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered 'None (0)'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered 'No (N)'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-13T22:16:26', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'dd74cb83-0aef-477e-8389-ad628a98830c' User entered '13 Sep 2020 22:16'	System	14 Sep 2020 03:16:28
	System	14 Sep 2020 03:16:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 5'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:07', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered 'None (0)'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:10', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered 'None (0)'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:12', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered 'None (0)'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered 'None (0)'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered 'None (0)'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:19', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered 'None (0)'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:23', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered 'No (N)'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-14T12:06:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '72323cc4-8c53-40dc-8ab0-5581bbefd04e' User entered '14 Sep 2020 12:06'	System	14 Sep 2020 17:06:28
	System	14 Sep 2020 17:06:28

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 6'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:56', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered 'None (0)'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:35:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered 'None (0)'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:36:03', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered 'None (0)'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:36:09', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered 'None (0)'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:36:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered 'None (0)'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:36:27', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered 'None (0)'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:36:35', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered 'No (N)'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-09-16T06:36:38', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '8ff9b242-19ac-4761-b31c-2283cd75243d' User entered '16 Sep 2020 06:36'	System	16 Sep 2020 11:36:41
	System	16 Sep 2020 11:36:41

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	10 Sep 2020 22:26:05
User entered 'Day 7'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 22:26:05

US3592127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 22:26:05

US3592127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:43:22

US3592127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:10
User entered '17 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:43:22

US3592127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 19:43:22

US3592127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:10
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:43:22

US3592127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:59:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:44:12

US3592127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	23 Sep 2020 19:44:12

US3592127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:52:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 14:21:24

US3592127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:52:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:22
User entered '25 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 14:21:24

US3592127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:52:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Sep 2020 14:21:24

US3592127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:52:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:22
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 14:21:24

US3592127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:52:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 14:21:39

US3592127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	26 Sep 2020 14:21:39

US3592127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 15:04:49

US3592127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:50
User entered '1 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 15:04:49

US3592127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 15:04:49

US3592127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:50
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:04:49

US3592127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:00:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 15:04:55

US3592127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	05 Oct 2020 15:04:55

US3592127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:01:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 22:44:37

US3592127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:01:43
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 22:44:37

US3592127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:01:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 22:44:37

US3592127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'VISIT3'	System	09 Oct 2020 22:44:37

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered '16:20'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered '9 Oct 2020 16:20'	System	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered '98.1' F	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered '63'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'bpm'	System	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered '16'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'breaths/min'	System	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered '130'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'mmHg'	System	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:15
User entered '66'	(b) (4), (b) (6)	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'mmHg'	System	09 Oct 2020 22:46:06

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10

US3592127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10

US3592127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:19
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 22:46:20

US3592127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:19
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 22:46:20

US3592127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 22:46:47

US3592127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:22
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 22:46:47

US3592127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:22
User entered '16:43'	(b) (4), (b) (6)	09 Oct 2020 22:46:47

US3592127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered '9 Oct 2020 16:43'	System	09 Oct 2020 22:46:47

US3592127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:24:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:02:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 22:46:56

US3592127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:10
User entered 'I'	System	09 Oct 2020 22:46:56

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 64'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-11T00:01:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be6501b7-e2af-4958-93b6-1bdd355edc3f' User entered 'No (N)'	System	11 Oct 2020 05:01:46
	System	11 Oct 2020 05:01:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-11T00:01:31', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be6501b7-e2af-4958-93b6-1bdd355edc3f'	System	11 Oct 2020 05:01:46
User entered 'No (N)'	System	11 Oct 2020 05:01:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-11T00:01:42', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'be6501b7-e2af-4958-93b6-1bdd355edc3f' User entered '11 Oct 2020 00:01:42'	System	11 Oct 2020 05:01:46
	System	11 Oct 2020 05:01:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 71'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-18T21:20:57', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b56fb9fd-4408-4193-9372-4c54e9d2076b' User entered 'No (N)'	System	19 Oct 2020 02:21:15
	System	19 Oct 2020 02:21:15

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-18T21:21:02', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b56fb9fd-4408-4193-9372-4c54e9d2076b'	System	19 Oct 2020 02:21:15
User entered 'No (N)'	System	19 Oct 2020 02:21:15

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-18T21:21:13', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b56fb9fd-4408-4193-9372-4c54e9d2076b' User entered '18 Oct 2020 21:21:13'	System	19 Oct 2020 02:21:15
	System	19 Oct 2020 02:21:15

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 78'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-25T02:55:34', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '088ed468-69f2-46d5-9e4e-2b821abe41f9'	System	25 Oct 2020 07:56:15
User entered 'No (N)'	System	25 Oct 2020 07:56:15

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-25T02:55:49', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '088ed468-69f2-46d5-9e4e-2b821abe41f9'	System	25 Oct 2020 07:56:15
User entered 'No (N)'	System	25 Oct 2020 07:56:15

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-10-25T02:56:13', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '088ed468-69f2-46d5-9e4e-2b821abe41f9' User entered '25 Oct 2020 02:56:13'	System	25 Oct 2020 07:56:15
	System	25 Oct 2020 07:56:15

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 92'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-08T01:56:35', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fd5a79e7-e20f-49bb-80bc-9b6c32321244'	System	08 Nov 2020 07:56:50
User entered 'No (N)'	System	08 Nov 2020 07:56:50

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-08T01:56:43', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fd5a79e7-e20f-49bb-80bc-9b6c32321244'	System	08 Nov 2020 07:56:50
User entered 'No (N)'	System	08 Nov 2020 07:56:50

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-08T01:56:48', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'fd5a79e7-e20f-49bb-80bc-9b6c32321244'	System	08 Nov 2020 07:56:50
User entered '08 Nov 2020 01:56:48'	System	08 Nov 2020 07:56:50

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered 'Day 99'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-15T01:31:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '12f8dbb4-8de4-4973-a150-d45afa3d2474'	System	17 Nov 2020 16:30:53
User entered 'No (N)'	System	17 Nov 2020 16:30:53

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-15T01:32:08', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '12f8dbb4-8de4-4973-a150-d45afa3d2474'	System	17 Nov 2020 16:30:53
User entered 'No (N)'	System	17 Nov 2020 16:30:53

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-15T01:32:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '12f8dbb4-8de4-4973-a150-d45afa3d2474'	System	17 Nov 2020 16:30:53
User entered '15 Nov 2020 01:32:16'	System	17 Nov 2020 16:30:53

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 23:26:46

US3592127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:26:40
Data entry locked.	System	11 Aug 2020 23:26:46
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 23:26:46

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-19T04:08:12', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'd024ce4f-fa54-4aff-b5d9-af09b103dbde' User entered 'No (N)'	System	19 Nov 2020 10:08:33
	System	19 Nov 2020 10:08:33

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-19T04:08:24', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'd024ce4f-fa54-4aff-b5d9-af09b103dbde' User entered 'No (N)'	System	19 Nov 2020 10:08:33
	System	19 Nov 2020 10:08:33

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-19T04:08:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'd024ce4f-fa54-4aff-b5d9-af09b103dbde' User entered '19 Nov 2020 04:08:28'	System	19 Nov 2020 10:08:33
	System	19 Nov 2020 10:08:33

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-26T15:30:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'c7a36ee1-10e1-41b1-b30b-2e0edd9b2596' User entered 'No (N)'	System	26 Nov 2020 21:31:22
	System	26 Nov 2020 21:31:22

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-26T15:31:04', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'c7a36ee1-10e1-41b1-b30b-2e0edd9b2596' User entered 'Yes (Y)'	System	26 Nov 2020 21:31:22
	System	26 Nov 2020 21:31:22

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-26T15:31:08', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'c7a36ee1-10e1-41b1-b30b-2e0edd9b2596'	System	26 Nov 2020 21:31:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Nov 2020 21:31:22

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-11-26T15:31:12', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'c7a36ee1-10e1-41b1-b30b-2e0edd9b2596' User entered '26 Nov 2020 15:31:12'	System	26 Nov 2020 21:31:22

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-04T14:39:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'de8bbc87-9269-4da3-ae0c-3f6c4e459fe5'	System	04 Dec 2020 20:40:45
User entered 'Yes (Y)'	System	04 Dec 2020 20:40:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-04T14:39:24', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'de8bbc87-9269-4da3-ae0c-3f6c4e459fe5'	System	04 Dec 2020 20:40:45
User entered 'No (N)'	System	04 Dec 2020 20:40:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-04T14:39:38', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'de8bbc87-9269-4da3-ae0c-3f6c4e459fe5'	System	04 Dec 2020 20:40:45
User entered 'No (N)'	System	04 Dec 2020 20:40:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-04T14:40:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'de8bbc87-9269-4da3-ae0c-3f6c4e459fe5'	System	04 Dec 2020 20:40:45
User entered 'Yes (Y)'	System	04 Dec 2020 20:40:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-04T14:40:27', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'de8bbc87-9269-4da3-ae0c-3f6c4e459fe5'	System	04 Dec 2020 20:40:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 20:40:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-04T14:40:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'de8bbc87-9269-4da3-ae0c-3f6c4e459fe5' User entered '04 Dec 2020 14:40:30'	System	04 Dec 2020 20:40:45
	System	04 Dec 2020 20:40:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-10T07:31:10', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bd46016c-703f-4645-bcea-a2a88a190e8d' User entered 'No (N)'	System	10 Dec 2020 13:31:38
	System	10 Dec 2020 13:31:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-10T07:31:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bd46016c-703f-4645-bcea-a2a88a190e8d' User entered 'No (N)'	System	10 Dec 2020 13:31:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-10T07:31:36', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'bd46016c-703f-4645-bcea-a2a88a190e8d' User entered '10 Dec 2020 07:31:36'	System	10 Dec 2020 13:31:38
	System	10 Dec 2020 13:31:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-17T02:53:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe53511-f895-40b4-b909-477b25dd5958'	System	17 Dec 2020 08:53:45
User entered 'No (N)'	System	17 Dec 2020 08:53:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-17T02:53:39', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe53511-f895-40b4-b909-477b25dd5958' User entered 'No (N)'	System	17 Dec 2020 08:53:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-17T02:53:43', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'abe53511-f895-40b4-b909-477b25dd5958' User entered '17 Dec 2020 02:53:43'	System	17 Dec 2020 08:53:45
	System	17 Dec 2020 08:53:45

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-24T03:28:02', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b01c5840-bb5d-4df0-be75-6d89e6f2f632'	System	24 Dec 2020 10:28:24
User entered 'No (N)'	System	24 Dec 2020 10:28:24

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-24T03:28:15', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b01c5840-bb5d-4df0-be75-6d89e6f2f632'	System	24 Dec 2020 10:28:24
User entered 'No (N)'	System	24 Dec 2020 10:28:24

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-24T03:28:19', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b01c5840-bb5d-4df0-be75-6d89e6f2f632' User entered '24 Dec 2020 03:28:19'	System	24 Dec 2020 10:28:24
	System	24 Dec 2020 10:28:24

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-31T14:52:45', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '33ab297b-9f11-45e0-b0ed-a3b67ea4f27c' User entered 'No (N)'	System	31 Dec 2020 21:53:08
	System	31 Dec 2020 21:53:08

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-31T14:52:54', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '33ab297b-9f11-45e0-b0ed-a3b67ea4f27c' User entered 'No (N)'	System	31 Dec 2020 21:53:08

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2020-12-31T14:53:04', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '33ab297b-9f11-45e0-b0ed-a3b67ea4f27c' User entered '31 Dec 2020 14:53:04'	System	31 Dec 2020 21:53:08
	System	31 Dec 2020 21:53:08

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2021-01-07T13:50:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '1f08e9c5-9ef9-461a-af9f-fe313b60eb2d' User entered 'No (N)'	System	07 Jan 2021 19:50:44

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2021-01-07T13:50:36', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '1f08e9c5-9ef9-461a-af9f-fe313b60eb2d'	System	07 Jan 2021 19:50:44
User entered 'No (N)'	System	07 Jan 2021 19:50:44

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18F4D913-9CDE-4788-8158-BD7EC56E534E)', Time: '2021-01-07T13:50:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '1f08e9c5-9ef9-461a-af9f-fe313b60eb2d' User entered '07 Jan 2021 13:50:40'	System	07 Jan 2021 19:50:44
	System	07 Jan 2021 19:50:44

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-14T14:22:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3f9efa6f-c1b6-4de1-8c94-2c3cb929f0d8' User entered 'No (N)'	System	14 Jan 2021 20:22:35
	System	14 Jan 2021 20:22:35

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-14T14:22:26', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3f9efa6f-c1b6-4de1-8c94-2c3cb929f0d8'	System	14 Jan 2021 20:22:35
User entered 'No (N)'	System	14 Jan 2021 20:22:35

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-14T14:22:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3f9efa6f-c1b6-4de1-8c94-2c3cb929f0d8' User entered '14 Jan 2021 14:22:30'	System	14 Jan 2021 20:22:35
	System	14 Jan 2021 20:22:35

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-21T15:06:58', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '939fe234-817a-41ae-bfa9-462f0249678d' User entered 'No (N)'	System	21 Jan 2021 22:07:07
	System	21 Jan 2021 22:07:07

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-21T15:07:02', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '939fe234-817a-41ae-bfa9-462f0249678d' User entered 'No (N)'	System	21 Jan 2021 22:07:07
	System	21 Jan 2021 22:07:07

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-21T15:07:05', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '939fe234-817a-41ae-bfa9-462f0249678d' User entered '21 Jan 2021 15:07:05'	System	21 Jan 2021 22:07:07
	System	21 Jan 2021 22:07:07

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-28T06:04:39', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'efe6b9ba-7fd9-4069-8c92-bab7707540a6'	System	28 Jan 2021 12:04:54
User entered 'No (N)'	System	28 Jan 2021 12:04:54

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-28T06:04:47', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'efe6b9ba-7fd9-4069-8c92-bab7707540a6'	System	28 Jan 2021 12:04:54
User entered 'No (N)'	System	28 Jan 2021 12:04:54

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-01-28T06:04:52', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'efe6b9ba-7fd9-4069-8c92-bab7707540a6' User entered '28 Jan 2021 06:04:52'	System	28 Jan 2021 12:04:54
	System	28 Jan 2021 12:04:54

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-04T09:42:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b393ba30-639b-4757-9d0c-5e2377dec7ab' User entered 'No (N)'	System	04 Feb 2021 15:43:16
	System	04 Feb 2021 15:43:16

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-04T09:43:05', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b393ba30-639b-4757-9d0c-5e2377dec7ab' User entered 'No (N)'	System	04 Feb 2021 15:43:16

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-04T09:43:14', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'b393ba30-639b-4757-9d0c-5e2377dec7ab'	System	04 Feb 2021 15:43:16
User entered '04 Feb 2021 09:43:14'	System	04 Feb 2021 15:43:16

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-11T05:29:43', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6182413a-2cd4-4f15-8a05-3a3ecdec6075' User entered 'No (N)'	System	11 Feb 2021 11:30:05
	System	11 Feb 2021 11:30:05

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-11T05:29:55', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6182413a-2cd4-4f15-8a05-3a3ecdec6075' User entered 'No (N)'	System	11 Feb 2021 11:30:05

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-11T05:29:59', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '6182413a-2cd4-4f15-8a05-3a3ecdec6075' User entered '11 Feb 2021 05:29:59'	System	11 Feb 2021 11:30:05
	System	11 Feb 2021 11:30:05

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-18T05:42:43', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '20ede508-9c6c-41d2-b6bc-a78164613ecc' User entered 'No (N)'	System	18 Feb 2021 11:43:00
	System	18 Feb 2021 11:43:00

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-18T05:42:49', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '20ede508-9c6c-41d2-b6bc-a78164613ecc' User entered 'No (N)'	System	18 Feb 2021 11:43:00

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-18T05:42:57', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '20ede508-9c6c-41d2-b6bc-a78164613ecc' User entered '18 Feb 2021 05:42:57'	System	18 Feb 2021 11:43:00

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-25T08:32:06', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3617703d-3848-4d3f-950f-25efb7a7807b' User entered 'No (N)'	System	25 Feb 2021 14:32:25
	System	25 Feb 2021 14:32:25

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-25T08:32:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3617703d-3848-4d3f-950f-25efb7a7807b' User entered 'No (N)'	System	25 Feb 2021 14:32:25

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-25T08:32:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '3617703d-3848-4d3f-950f-25efb7a7807b'	System	25 Feb 2021 14:32:25
User entered '25 Feb 2021 08:32:22'	System	25 Feb 2021 14:32:25

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-04T07:15:12', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '79d2cc70-c331-4961-913e-28be3e230273'	System	04 Mar 2021 13:15:38
User entered 'No (N)'	System	04 Mar 2021 13:15:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-04T07:15:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '79d2cc70-c331-4961-913e-28be3e230273'	System	04 Mar 2021 13:15:38
User entered 'No (N)'	System	04 Mar 2021 13:15:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-04T07:15:32', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '79d2cc70-c331-4961-913e-28be3e230273' User entered '04 Mar 2021 07:15:32'	System	04 Mar 2021 13:15:38
	System	04 Mar 2021 13:15:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-11T00:01:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '185f9c4c-7eba-4249-9502-0490606edc3d' User entered 'No (N)'	System	11 Mar 2021 06:01:32
	System	11 Mar 2021 06:01:32

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-11T00:01:22', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '185f9c4c-7eba-4249-9502-0490606edc3d' User entered 'No (N)'	System	11 Mar 2021 06:01:32

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-11T00:01:26', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '185f9c4c-7eba-4249-9502-0490606edc3d' User entered '11 Mar 2021 00:01:26'	System	11 Mar 2021 06:01:32
	System	11 Mar 2021 06:01:32

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-18T00:01:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'ae0aef9a-cd29-4370-bad5-8d42464c1dd6'	System	18 Mar 2021 05:01:30
User entered 'No (N)'	System	18 Mar 2021 05:01:30

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-18T00:01:24', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'ae0aef9a-cd29-4370-bad5-8d42464c1dd6'	System	18 Mar 2021 05:01:30
User entered 'No (N)'	System	18 Mar 2021 05:01:30

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-18T00:01:27', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'ae0aef9a-cd29-4370-bad5-8d42464c1dd6' User entered '18 Mar 2021 00:01:27'	System	18 Mar 2021 05:01:30
	System	18 Mar 2021 05:01:30

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-25T00:15:11', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '33bbd095-4eee-4048-a4f8-a0e0ecccc8e' User entered 'No (N)'	System	25 Mar 2021 05:15:26

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-25T00:15:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '33bbd095-4eee-4048-a4f8-a0e0ecccc8e'	System	25 Mar 2021 05:15:26
User entered 'No (N)'	System	25 Mar 2021 05:15:26

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-03-25T00:15:23', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '33bbd095-4eee-4048-a4f8-a0e0ecccc8e' User entered '25 Mar 2021 00:15:23'	System	25 Mar 2021 05:15:26

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-01T12:02:17', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f7af80f7-e075-40c7-9df8-e858539668b0' User entered 'Yes (Y)'	System	01 Apr 2021 17:05:38
	System	01 Apr 2021 17:05:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-01T12:02:28', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f7af80f7-e075-40c7-9df8-e858539668b0' User entered 'No (N)'	System	01 Apr 2021 17:05:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-01T12:02:35', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f7af80f7-e075-40c7-9df8-e858539668b0' User entered 'No (N)'	System	01 Apr 2021 17:05:38
	System	01 Apr 2021 17:05:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-01T12:02:43', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f7af80f7-e075-40c7-9df8-e858539668b0'	System	01 Apr 2021 17:05:38
User entered 'Yes (Y)'	System	01 Apr 2021 17:05:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-01T12:02:50', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f7af80f7-e075-40c7-9df8-e858539668b0'	System	01 Apr 2021 17:05:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Apr 2021 17:05:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-01T12:03:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'f7af80f7-e075-40c7-9df8-e858539668b0' User entered '01 Apr 2021 12:03:16'	System	01 Apr 2021 17:05:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-08T07:34:10', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'df65f504-fcb2-47de-a3bf-9a67d0b9a2ac' User entered 'Yes (Y)'	System	08 Apr 2021 12:34:46
	System	08 Apr 2021 12:34:46

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-08T07:34:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'df65f504-fcb2-47de-a3bf-9a67d0b9a2ac'	System	08 Apr 2021 12:34:46
User entered 'No (N)'	System	08 Apr 2021 12:34:46

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-08T07:34:26', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'df65f504-fcb2-47de-a3bf-9a67d0b9a2ac'	System	08 Apr 2021 12:34:46
User entered 'No (N)'	System	08 Apr 2021 12:34:46

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-08T07:34:36', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'df65f504-fcb2-47de-a3bf-9a67d0b9a2ac' User entered 'No (N)'	System	08 Apr 2021 12:34:46

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-08T07:34:42', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'df65f504-fcb2-47de-a3bf-9a67d0b9a2ac'	System	08 Apr 2021 12:34:46
User entered '08 Apr 2021 07:34:42'	System	08 Apr 2021 12:34:46

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-15T10:10:32', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7eb633dd-17bc-4bec-80d9-65d361e0c4c7'	System	15 Apr 2021 15:11:52
User entered 'Yes (Y)'	System	15 Apr 2021 15:11:52

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-15T10:10:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7eb633dd-17bc-4bec-80d9-65d361e0c4c7'	System	15 Apr 2021 15:11:52
User entered 'No (N)'	System	15 Apr 2021 15:11:52

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-15T10:10:54', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7eb633dd-17bc-4bec-80d9-65d361e0c4c7'	System	15 Apr 2021 15:11:52
User entered 'No (N)'	System	15 Apr 2021 15:11:52

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-15T10:11:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7eb633dd-17bc-4bec-80d9-65d361e0c4c7'	System	15 Apr 2021 15:11:52
User entered 'Yes (Y)'	System	15 Apr 2021 15:11:52

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-15T10:11:37', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7eb633dd-17bc-4bec-80d9-65d361e0c4c7'	System	15 Apr 2021 15:11:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Apr 2021 15:11:52

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-15T10:11:40', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '7eb633dd-17bc-4bec-80d9-65d361e0c4c7' User entered '15 Apr 2021 10:11:40'	System	15 Apr 2021 15:11:52
	System	15 Apr 2021 15:11:52

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-22T05:58:19', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87604147-58dd-463b-b6d8-4f3dedd42433'	System	22 Apr 2021 10:58:33
User entered 'No (N)'	System	22 Apr 2021 10:58:33

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-22T05:58:25', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87604147-58dd-463b-b6d8-4f3dedd42433'	System	22 Apr 2021 10:58:33
User entered 'No (N)'	System	22 Apr 2021 10:58:33

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-22T05:58:29', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '87604147-58dd-463b-b6d8-4f3dedd42433'	System	22 Apr 2021 10:58:33
User entered '22 Apr 2021 05:58:29'	System	22 Apr 2021 10:58:33

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-29T03:15:18', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '70559976-b26a-48d8-a7c8-e108d6811fc7' User entered 'No (N)'	System	29 Apr 2021 08:15:38
	System	29 Apr 2021 08:15:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

Have you been exposed to someone with 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 (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-29T03:15:30', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '70559976-b26a-48d8-a7c8-e108d6811fc7'	System	29 Apr 2021 08:15:38
User entered 'No (N)'	System	29 Apr 2021 08:15:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-04-29T03:15:34', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: '70559976-b26a-48d8-a7c8-e108d6811fc7' User entered '29 Apr 2021 03:15:34'	System	29 Apr 2021 08:15:38
	System	29 Apr 2021 08:15:38

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:27:48

US3592127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:27:48
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:27:48

US3592127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:55:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:12:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-27T21:54:16', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a54310e9-604e-4862-bdfc-7ab19284e540'	System	28 Feb 2021 03:55:47
User entered 'No (N)'	System	28 Feb 2021 03:55:47

US3592127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:55:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:12:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE35D876-0103-42E9-9121-956BF7C63EB0)', Time: '2021-02-27T21:54:24', User OID: 'PatientReportedOutcome (US3592127)', ODM File OID: 'a54310e9-604e-4862-bdfc-7ab19284e540' User entered '27 Feb 2021 21:54:24'	System	28 Feb 2021 03:55:47
	System	28 Feb 2021 03:55:47

US3592127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:46:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:25:02

US3592127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:46:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:15
User entered '3 Nov 2020'	(b) (4), (b) (6)	11 Feb 2021 16:25:02

US3592127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:46:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 16:25:02

US3592127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:46:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:15
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 16:25:02

US3592127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:46:55
User closed query 'Please add date of contact on source reflects 03 Nov 2020.' (Site from CRA).	(b) (4)	
Query 'Please add date of contact on source reflects 03 Nov 2020.' answered with 'page completed ' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:37:06
User opened query 'Please add date of contact on source reflects 03 Nov 2020.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:28:22
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:12:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 19:11:16
	(b) (4), (b) (6)	08 Dec 2020 22:24:10

US3592127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:26:01
User entered 'l'	System	08 Dec 2020 22:24:10

US3592127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 22:24:23

US3592127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:10:54
User entered '8 Dec 2020'	(b) (4), (b) (6)	08 Dec 2020 22:24:23

US3592127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:10:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Dec 2020 22:24:23

US3592127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:10:54
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:24:23

US3592127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:11:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 22:24:27

US3592127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User entered 'l'	System	08 Dec 2020 22:24:27

US3592127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:14:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:40:09

US3592127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:14:13
User entered '8 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:40:09

US3592127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:14:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Jan 2021 18:40:09

US3592127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:14:13
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:40:09

US3592127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:14:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:40:18

US3592127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User entered 'l'	System	18 Jan 2021 18:40:18

US3592127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:27:16

US3592127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:38
User entered '8 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 16:27:16

US3592127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 16:27:16

US3592127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:38
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 16:27:16

US3592127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:55:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:27:20

US3592127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:09:59
User entered 'l'	System	11 Feb 2021 16:27:20

US3592127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:26:05

US3592127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:26:05

US3592127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[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 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:26:05

US3592127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered 'VISIT4'	System	01 Mar 2021 16:26:05

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '11:13'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered '25 Feb 2021 11:13'	System	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '64'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered 'bpm'	System	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered 'breaths/min'	System	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '130'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered 'mmHg'	System	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '71'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered 'mmHg'	System	05 Apr 2021 16:48:43

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45

US3592127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45

US3592127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:26:34

US3592127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:26:34

US3592127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:27:09

US3592127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:27:09

US3592127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Mar 2021 18:27:26
User entered '11:36' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 18:27:26
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 16:27:09
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 16:27:09

US3592127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered '25 Feb 2021 11:36'	System	09 Mar 2021 18:27:26
User entered empty.	System	01 Mar 2021 16:27:09

US3592127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:27:16

US3592127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:12:45
User entered 'l'	System	01 Mar 2021 16:27:16

US3592127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:55:59

US3592127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '7 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:55:59

US3592127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:55:59

US3592127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:55:59

US3592127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:56:09

US3592127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Apr 2021 14:56:09

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:36:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:05:46
Query 'Please reconcile and enter severity page as required. Please note that there is an O2 value of 93 present on symptom log on 14Nov2020 which should be recorded on severity page as well.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:45:33
User opened query 'Please reconcile and enter severity page as required. Please note that there is an O2 value of 93 present on symptom log on 14Nov2020 which should be recorded on severity page as well.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:22:58
User entered '12 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:15:45

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:36:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:05:46
User entered '16:58'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:15:45

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:36:53
User entered '12 Nov 2020 16:58'	System	14 Nov 2020 00:15:45

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:16

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:36:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:05:46
User entered 'Safety Call (Safety Call)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:15:45

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:36:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:05:46
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:15:45

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 1 (Day 1)'	(b) (4) Diandra Henriques (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '11 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Severe (Severe)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:17:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 2 (Day 2)'	(b) (4) Diandra Henriques (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '12 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:18:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 3 (Day 3)'	(b) (4) Diandra Henriques (b) (4)	14 Nov 2020 00:19:46

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '95'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '37.1' C	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:19:46

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User closed query 'Please reconcile and add all dates since 14Nov2020. As a reminder symptom log is to be entered within 24 hrs of illness call completion' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:45:43
Query 'Please reconcile and add all dates since 14Nov2020. As a reminder symptom log is to be entered within 24 hrs of illness call completion' answered with 'log has been updated ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 17:25:03
User opened query 'Please reconcile and add all dates since 14Nov2020. As a reminder symptom log is to be entered within 24 hrs of illness call completion' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:23:28
User entered '14 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '93'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '98.0' F	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 20:22:58

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '15 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '95'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '98.0' F	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:26:47

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '16 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '94'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '97.5' F	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:28:53

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '17 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '95'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '96.6' F	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:30:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '18 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '94'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '98.3' F	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:32:00

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '19 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '97'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '96.8' F	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:35:25

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '20 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '97.6' F	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:36:55

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '21 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '94'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '97.0' F	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 17:39:30

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'Per ETRTR: Please add Symptoms after 22Nov20. Per protocol, Symptoms should be gathered 14 days after Illness Visit Day 1 or until Symptoms are recovered, whichever is later. Per CRF Guidelines, Data entry for Symptoms log is every 24 Hrs. Thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:46:59
Query 'Per ETRTR: Please add Symptoms after 22Nov20. Per protocol, Symptoms should be gathered 14 days after Illness Visit Day 1 or until Symptoms are recovered, whichever is later. Per CRF Guidelines, Data entry for Symptoms log is every 24 Hrs. Thanks.' answered with 'Entry Completed' (Site from CRA).	(b) (4), (b) (6)	05 Dec 2020 16:48:05
User opened query 'Per ETRTR: Please add Symptoms after 22Nov20. Per protocol, Symptoms should be gathered 14 days after Illness Visit Day 1 or until Symptoms are recovered, whichever is later. Per CRF Guidelines, Data entry for Symptoms log is every 24 Hrs. Thanks.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 23:46:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '22 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '96'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered '98.1' F	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:09
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 18:18:48

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '23 Nov 2020'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '0'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '95'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '96.2' F	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:37:27

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '24 Nov 2020'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '0'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '97'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '94.5' F	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:41:07

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '25 Nov 2020'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '0'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '96'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '97.0' F	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:43:03

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query ' Per CDM: Per sponsor review, please verify data for Symptom Day Day 17 as it does not follow sequence in days. Please consider to update to Day 16 and the rest of the Symptom days accordingly, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 09:37:01
Query ' Per CDM: Per sponsor review, please verify data for Symptom Day Day 17 as it does not follow sequence in days. Please consider to update to Day 16 and the rest of the Symptom days accordingly, else clarify. ' answered with 'Sx d16 was missed, row added with "assessment not done" deviation recorded' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:13:31
User opened query ' Per CDM: Per sponsor review, please verify data for Symptom Day Day 17 as it does not follow sequence in days. Please consider to update to Day 16 and the rest of the Symptom days accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:29:41
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '27 Nov 2020'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '0'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '97'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '97.7' F	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:46:01

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'Please add Symptom Days as per protocol, subject Negative on 11 Dec 2020.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:10:50
Query 'Please add Symptom Days as per protocol, subject Negative on 11 Dec 2020.' answered with 'updatd ' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:32:32
User opened query 'Please add Symptom Days as per protocol, subject Negative on 11 Dec 2020.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:31:48
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '28 Nov 2020'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '0'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '97'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered '%'	System	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered '97.4' F	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:04
User entered 'None (None)'	(b) (4), (b) (6)	05 Dec 2020 16:47:44

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Day 16 (Day 16)'	(b) (4) Diandra Henriques (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '26 Nov 2020'	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'l'	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
User entered empty.	System	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 17:12:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 05:51:39
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE has been entered.' (Site from System).	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:10:03
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 14:09:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 14:09:37
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	21 Nov 2020 14:09:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:09:37
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:44:54
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	20 Nov 2020 19:44:54
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered by data change (Site from System).	System	20 Nov 2020 19:44:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 19:44:54
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:44:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:44:44

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	20 Nov 2020 19:44:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 19:44:44
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 00:20:08
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:15
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:20:08

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:10
User entered 'l'	System	20 Nov 2020 19:44:44

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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Generated On: 11 Aug 2021 22:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered '14 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered '14 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered '93'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Folder: Covid-19 Assessment 12 Nov 2020

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
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[Acute Renal Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
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US3592127

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:40
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 17:23:06

US3592127

Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:55:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:37:24
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:56:36
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 16:30:05

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:55:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User accepted default value 'Day 3 (Day 3)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered '15 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:55:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User accepted default value 'Day 5 (Day 5)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered '17 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:55:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User accepted default value 'Day 7 (Day 7)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered '19 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:55:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User accepted default value 'Day 9 (Day 9)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:12:25
User closed query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:43:51
Query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 19:37:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:36:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User opened query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:32:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:06:17
Query 'Data is required. Please complete.' answered with 'pending ' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 17:24:06
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 14:15:02
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:17:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is recorded under Illness visit day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 07:10:35
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is recorded under Illness visit day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'D9 was entered on req as 26 NOV 2020 - Will reconcile with PPD Central Lab - DCR sent 15 APR 2021' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	15 Apr 2021 21:42:22
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is recorded under Illness visit day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:13:06
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 15:40:08
User entered '21 Nov 2020' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 15:40:08
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:12:25
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:36:04

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:31
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:55:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User accepted default value 'Day 14 (Day 14)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 is recorded under Illness Visit Day 14 in EDC, however the same is reported under COVID PCR Saliva Day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 09:37:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 is recorded under Illness Visit Day 14 in EDC, however the same is reported under COVID PCR Saliva Day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'Confirming this date for this sample. Collection date entered incorrectly on req for D9, will reconcile with PPD Central Lab' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 15:40:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 is recorded under Illness Visit Day 14 in EDC, however the same is reported under COVID PCR Saliva Day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 04:02:24
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:12:25
User closed query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:43:56
Query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 19:37:25
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	09 Dec 2020 19:36:25
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:35

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User opened query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).		24 Nov 2020 13:32:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:17:45
Query 'Data is required. Please complete.' answered with 'pending ' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 17:24:11
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 14:15:02
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:12:25
User entered '26 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	09 Dec 2020 19:36:25
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:55:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User accepted default value 'Day 21 (Day 21)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:12:25
User closed query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:44:01
Query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 19:37:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:35:47
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User opened query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:32:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:18:29
Query 'Data is required. Please complete.' answered with 'pending ' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 17:24:16
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 14:15:02
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:12:25
User entered '3 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:35:47
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:55:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User accepted default value 'Day 28 (Day 28)'	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:12:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 18:33:45
User closed query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:44:50
Query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 19:37:13
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:37:08
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User opened query 'Per CDM RQ: Thanks for the response. Please complete the data whenever available, also consider to keep this query in open status till data is updated.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:32:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:19:48
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 17:24:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 14:15:02
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:12:25
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 18:33:45
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:49
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Nov 2020 14:15:02

US3592127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:25
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:59
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:12:07

US3592127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:25
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please update the sample details dated 11DEC2020 in EDC as its reported at DAY 28 under Illness visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 05:28:52
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please update the sample details dated 11DEC2020 in EDC as its reported at DAY 28 under Illness visit.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:33:55
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please update the sample details dated 11DEC2020 in EDC as its reported at DAY 28 under Illness visit.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:43:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:43:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'visit added convalescent visit ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 16:37:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:58:29

US3592127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:59
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:12:07

US3592127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:25
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:59
User entered 'Clinic (Clinic)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:12:07

US3592127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:25
User entered 'SICKD1'	System	14 Nov 2020 00:12:07

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '10:35'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User entered '13 Nov 2020 10:35'	System	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '178.0' cm	Diandra Henriques (b) (4)	14 Nov 2020 00:14:31
DataPoint set to visible.	(b) (4) System	14 Nov 2020 00:12:07

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '101.9' kg	Diandra Henriques (b) (4)	14 Nov 2020 00:14:31
DataPoint set to visible.	(b) (4) System	14 Nov 2020 00:12:07

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '37.1' C	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered 'Oral (Oral)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '58'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User entered 'bpm'	System	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '16'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User entered 'breaths/min'	System	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '134'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User entered 'mmHg'	System	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:55
User entered '67'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33
User entered 'mmHg'	System	14 Nov 2020 00:14:31

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33

US3592127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:33

US3592127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:39
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:59
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:41

US3592127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:39
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:11:59
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:14:41

US3592127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:55:16

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:04
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:15:17

US3592127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:09:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:12:04
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:15:17

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 16:35:09

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:45
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 16:35:09

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:45
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Dec 2020 16:35:09

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:53
User entered 'SICKD28'	System	16 Dec 2020 16:35:09

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '13:39'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User entered '11 Dec 2020 13:39'	System	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '178.0' cm	(b) (4), (b) (6)	16 Dec 2020 16:36:12
DataPoint set to visible.	System	16 Dec 2020 16:35:09

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '102.1' kg	(b) (4), (b) (6)	16 Dec 2020 16:36:12
DataPoint set to visible.	System	16 Dec 2020 16:35:09

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '98.0' F	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '75'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User entered 'bpm'	System	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '16'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User entered 'breaths/min'	System	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '117'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User entered 'mmHg'	System	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:16:55
User entered '71'	(b) (4), (b) (6)	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00
User entered 'mmHg'	System	16 Dec 2020 16:36:12

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:00

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:08
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:17:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 16:36:35

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:08
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:17:00
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 16:36:35

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:55:16

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:17:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 16:36:53

US3592127

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:14
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:17:04
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 16:36:53

US3592127

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:32:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:42:54

US3592127

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:32:50
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:42:54

US3592127

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:32:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Jan 2021 18:42:54

US3592127

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 18:42:54

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:33:09
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:56:52

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:33:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:56:52

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:33:09
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:33:09
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:33:09
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:49:21
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:33:09
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:49:21
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:33:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'I'	System	18 Jan 2021 18:43:09

US3592127

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'I'	System	18 Jan 2021 18:43:09

US3592127

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '106.8' kg	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered empty.	System	18 Jan 2021 18:44:32
DataPoint set to visible.	System	18 Jan 2021 18:43:09

US3592127

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '106.8' kg	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered empty.	System	18 Jan 2021 18:44:32
DataPoint set to visible.	System	18 Jan 2021 18:43:09

US3592127

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User accepted default value 'Pre-Dose (PREDOSE)'		18 Jan 2021 18:44:32

US3592127

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '13:33'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered '14 Jan 2021 13:33'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '36.8' C	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '63'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'bpm'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '16'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'breaths/min'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '127'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'mmHg'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '66'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'mmHg'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '106.8' kg	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered empty.	System	18 Jan 2021 18:44:32
DataPoint set to visible.	System	18 Jan 2021 18:43:09

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User accepted default value 'Post-Dose (POSTDOSE)'		18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '14:45'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered '14 Jan 2021 14:45'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '98.2' F	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '57'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'bpm'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '16'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'breaths/min'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '109'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'mmHg'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:34:59
User entered '67'	(b) (4), (b) (6)	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'mmHg'	System	18 Jan 2021 18:44:32

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:45:20

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:04
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:45:20

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:23
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:23
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'mRNA-1273'	System	18 Jan 2021 18:45:35
DataPoint set to visible.	System	18 Jan 2021 18:43:09

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:23
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:23
User entered '14:13'	(b) (4), (b) (6)	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered '14 Jan 2021 14:13'	System	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:23
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
DataPoint Verified.		09 Feb 2021 19:35:23
User entered 'ONCE'	System	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'INTRAMUSCULAR'	System	18 Jan 2021 18:45:35

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:45:57

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:28
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:45:57

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:28
User entered '13:40'	(b) (4), (b) (6)	18 Jan 2021 18:45:57

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered '14 Jan 2021 13:40'	System	18 Jan 2021 18:45:57

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:46:14

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:32
User entered '14 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 18:46:14

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:35:32
User entered '13:44'	(b) (4), (b) (6)	18 Jan 2021 18:46:14

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered '14 Jan 2021 13:44'	System	18 Jan 2021 18:46:14

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'Please add OL-D8 Safety Call as per source.' (Site from CRA).	(b) (4)	18 Feb 2021 16:36:54
Query 'Please add OL-D8 Safety Call as per source.' answered with 'page compleeted ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:30:36
User opened query 'Please add OL-D8 Safety Call as per source.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:36:56
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:35:36
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:45:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:45:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 21:45:39
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 18:46:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 18:46:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 18:46:19

US3592127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:47
User entered 'l'	System	19 Jan 2021 21:45:39
User entered empty.	System	18 Jan 2021 18:46:31
User entered 'l'	System	18 Jan 2021 18:46:19

US3592127

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:01:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:26:37

US3592127

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:01:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:01
User entered '21 Jan 2021'	(b) (4), (b) (6)	11 Feb 2021 16:26:37

US3592127

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:01:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 16:26:37

US3592127

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:01:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:01
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 16:26:37

US3592127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:01:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:26:45

US3592127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:01:53
User entered 'l'	System	11 Feb 2021 16:26:45

US3592127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:01:53
User entered 'I'	System	11 Feb 2021 16:26:45
DataPoint set to visible.	System	11 Feb 2021 16:26:45

US3592127

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:27:52

US3592127

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:27:52

US3592127

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:27:52

US3592127

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'OLD29'	System	01 Mar 2021 16:27:52

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '11:13'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered '25 Feb 2021 11:13'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '64'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'bpm'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'breaths/min'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '130'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'mmHg'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '71'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'mmHg'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '12:29'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered '25 Feb 2021 12:29'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '61'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'bpm'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'breaths/min'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '146'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'mmHg'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '80'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'mmHg'	System	01 Mar 2021 16:29:18

US3592127

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:28:06

US3592127

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:28:06

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

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)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'mRNA-1273'	System	01 Mar 2021 16:29:47
DataPoint set to visible.	System	11 Feb 2021 16:26:45

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '11:57'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered '25 Feb 2021 11:57'	System	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'ONCE'	System	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 16:29:47

US3592127

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:52

US3592127

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:41
User entered 'l'	System	01 Mar 2021 16:29:52

US3592127

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:36:37
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:27:53

US3592127

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:36:37
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:27:53

US3592127

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:36:37
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:27:53

US3592127

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:36:37
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:27:53

US3592127

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:36:37
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:28:04

US3592127

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:36:37
User entered 'l'	System	09 Mar 2021 18:28:04

US3592127

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:32:55

US3592127

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'protocol deviation completed ' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 07:05:17
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'protocol deviation completed ' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 16:49:48
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Mar 2021 16:32:55
User entered '16 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 16:32:55

US3592127

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:32:55

US3592127

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User entered 'OLD57'	System	19 Mar 2021 16:32:55

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '13:15'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User entered '16 Mar 2021 13:15'	System	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '62'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User entered 'bpm'	System	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User entered 'breaths/min'	System	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '146'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User entered 'mmHg'	System	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '75'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User entered 'mmHg'	System	19 Mar 2021 16:33:39

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28

US3592127

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28

US3592127

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:34:06

US3592127

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:34:06

US3592127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:34:00

US3592127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:34:00

US3592127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '13:21'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:34:00

US3592127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:36:28
User entered '16 Mar 2021 13:21'	System	19 Mar 2021 16:34:00

US3592127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:55:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:40
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:13:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:24:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Sep 2020 17:05:46

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:11:34
User entered 'USA-US103-2020-mRNA-1273-P301000010'	System	19 Nov 2020 14:10:52
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 14:10:52

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:22
Data point term sent to Coder	System	23 Nov 2020 20:59:34
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:59:27
' canceled (Site from System).		
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:24:29
' (Site from System).		
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 20:25:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 20:25:52
Data point term sent to Coder	System	18 Nov 2020 20:25:34
User entered 'symptomatic covid-19'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User closed query 'Please reconcile as illness visit = MAAE per protocol' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:44:08
Query 'Please reconcile as illness visit = MAAE per protocol' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:08:57
User opened query 'Please reconcile as illness visit = MAAE per protocol' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:21:02
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User closed query 'Please verify if this should be NO' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:44:04
Query 'Please verify if this should be NO' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:08:57
User opened query 'Please verify if this should be NO' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:21:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User closed query 'Please verify if this should be 11Nov2020 as that was when symptoms began' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:44:11
Query 'Please verify if this should be 11Nov2020 as that was when symptoms began' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:17
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:08:57
User opened query 'Please verify if this should be 11Nov2020 as that was when symptoms began' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:21:55
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:25
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Dec 2020 19:31:44
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 19:31:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:31:44
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Dec 2020 19:31:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:28
User closed query 'PV Query: Please confirm the event end date (considered when symptoms resolved) or update the COVID-19 symptom log as mild runny nose was reported on 28 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 13:52:25
Query 'PV Query: Please confirm the event end date (considered when symptoms resolved) or update the COVID-19 symptom log as mild runny nose was reported on 28 Nov 2020.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	18 Jan 2021 18:32:24
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 18:32:15
User opened query 'PV Query: Please confirm the event end date (considered when symptoms resolved) or update the COVID-19 symptom log as mild runny nose was reported on 28 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:38:37
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 06:47:44
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:17:27
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:31:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 19:31:35
User entered '28 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:31:35
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'updated to resolved' (Site from System).	(b) (4), (b) (6)	09 Dec 2020 19:31:21
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		09 Dec 2020 19:31:08

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 22:19:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:26
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:08:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:08:57
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:08:57
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:25:30
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:26
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).	System	19 Nov 2020 20:09:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:09:33
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	18 Nov 2020 20:25:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:40:39
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:09:56
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:08:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:08:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:08:57
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:26:09
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:25:30
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:26
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:08:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:08:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:08:57
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:25:30
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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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.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:41
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:17:09
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'changed to NA' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:32:09
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 19:31:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:31:08
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 22:19:04
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 19:37:41
DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 16:38:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 16:38:49
DataPoint Verified.	(D) (4), (D) (6)	24 Nov 2020 17:14:26
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:41
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 14:29:30
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 14:29:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 19:37:41
User entered '0' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 14:29:30
DataPoint Un-verified.	(D) (4), (b) (6)	14 Dec 2020 16:38:49
User entered '1' reason for change: New Information	(b) (4), (b) (6)	14 Dec 2020 16:38:49
DataPoint Verified.	(D) (4), (D) (6)	24 Nov 2020 17:14:26
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:41
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:17:44
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated to resolve' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:32:56
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 19:31:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 19:31:08
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 22:19:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
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) (4), (b) (6)	10 Dec 2020 18:17:50
User closed query 'PV Query: Please provide the result for COVID-19 diagnostic test.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:17:20
Query 'PV Query: Please provide the result for COVID-19 diagnostic test.' answered with 'page has been completed' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:33:33
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 'no medication reported by subject' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:33:13
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)	01 Dec 2020 22:20:10
User opened query 'PV Query: Please provide the result for COVID-19 diagnostic test.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 22:19:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 20:09:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 20:09:33
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 20:25:30
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 20:09:33
User entered '1'	System	18 Nov 2020 20:25:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:08:57
User entered '0'	System	18 Nov 2020 20:25:30

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:12:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 16:12:51
Data point term sent to Coder	System	23 Apr 2021 16:01:14
User entered 'Left knee pain post surgical'	(b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User entered empty.	System	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User entered empty.	System	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User entered '0'	System	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33
User entered '0'	System	23 Apr 2021 16:00:31

US3592127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:38:33

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Ear buzzing - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:06:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:06:59
Data point term sent to Coder	System	23 Apr 2021 16:02:15
User entered 'Buzzing in right ear'	(b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:01:38

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:04:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 16:04:00
Data point term sent to Coder	System	23 Apr 2021 16:03:16
User entered 'Vertigo'	(b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:55:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:02:42

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:04:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:04:52
Data point term sent to Coder	System	23 Apr 2021 16:04:18
User entered 'Vomiting'	(b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:55:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:03:28

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as SOC: Endocrine disorders, HLGT: Parathyroid gland disorders, HLT: Hyperparathyroid disorders, PT: Hyperparathyroidism, LLT: Hyperparathyroidism - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:05:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:05:51
Data point term sent to Coder	System	23 Apr 2021 16:05:20
User entered 'hyperparathyroidism'	(b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:55:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:04:24

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypercalcaemia, LLT: Hypercalcemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:05:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:05:51
Data point term sent to Coder	System	23 Apr 2021 16:05:19
User entered 'hypercalcemia'	(b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:04:59

US3592127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:55:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:04:59

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:55:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:40
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:24:33

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:27:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:27:21
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	14 Aug 2020 16:25:43 14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:06:09
Query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 17:17:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Sep 2020 17:17:01
User opened query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 12:18:49
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Cardiac Prophylaxis'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '81'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:48:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:25:26
User entered 'UN UNK 2010'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:25:26

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 17:55:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:07
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:54 24 Nov 2020 17:14:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:28:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:28:26
Data point term sent to Coder User entered 'Ozempic'	System (b) (4), (b) (6)	14 Aug 2020 16:27:49 14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Diabetes Mellitus Type II'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'every week (QS)'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:48:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:27:05
User entered 'UN Feb 2019'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	14 Aug 2020 16:27:05

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:00
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:55 24 Nov 2020 17:14:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:29:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:29:17
Data point term sent to Coder User entered 'Flonase'	System (b) (4), (b) (6)	14 Aug 2020 16:28:53 14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'allergic rhinitis'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'l'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Spray'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:48:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:28:21
User entered 'UN UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:28:21

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:29
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:55 24 Nov 2020 17:14:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:30:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:30:22
Data point term sent to Coder User entered 'Effexor'	System (b) (4), (b) (6)	14 Aug 2020 16:29:56 14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Depression'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '150'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:48:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:29:02
User entered 'UN UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:29:02

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 17:57:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:57:01
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:55 24 Nov 2020 17:14:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:43:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:43:21
Data point term sent to Coder	System	14 Aug 2020 16:37:10
Data point term sent to Coder	System	14 Aug 2020 16:32:01
User entered 'Celebrex'	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Bilateral Knee Osteoarthritis'	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '200'	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:36:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 16:36:13
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:36:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:31:50
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:36:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 16:36:13
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:36:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:31:50
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:49:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:36:13
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 16:36:13
User entered 'UN UNK 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:36:13
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 16:31:50
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:36:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 16:36:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:36:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:31:50
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:36:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 16:36:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:36:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:31:50
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:36:13
User entered empty.	System	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:36:13
User entered empty.	System	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:36:13
User entered empty.	System	14 Aug 2020 16:31:50

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 17:57:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:01
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:55 24 Nov 2020 17:14:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:39:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:39:22
Data point term sent to Coder User entered 'Multivitamin'	System (b) (4), (b) (6)	14 Aug 2020 16:38:16 14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Nutritional Supplement'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:49:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:37:27
User entered 'UN Aug 2019'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:37:27

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: ASCORBIC ACID;BOSWELLIA SERRATA;CHONDROITIN SULFATE SODIUM;COLECALCIFEROL;GLUCOSAMINE SULFATE POTASSIUM CHLORIDE;MANGANESE SULFATE;METHYLSULFONYLMETHANE;SODI UM BORATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:00
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:55 24 Nov 2020 17:14:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: ASCORBIC ACID;BOSWELLIA SERRATA;CHONDROITIN SULFATE SODIUM;COLECALCIFEROL;GLUCOSAMINE SULFATE POTASSIUM CHLORIDE;MANGANESE SULFATE;METHYLSULFONYLMETHANE;SODI UM BORATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 08:16:39

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 08:16:39
Data point term sent to Coder	System	23 Aug 2020 15:00:53
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	23 Aug 2020 15:00:42
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'active ingredients added ' (Site from System).	(b) (4), (b) (6)	23 Aug 2020 15:00:42
User entered 'OSTEOBIFLEX (BOSWELLIA, VITAMIN C, MANGANESE, VITAMIN D, GLUCOSAMINE, CHONDROITIN, METHYLSULFONYLMETHANE (MSM), COLLAGEN SERRATA)' reason for change: New Information	(b) (4), (b) (6)	23 Aug 2020 15:00:27
User entered 'OSTEOBIFLEX (Boswellia, Vitamin C, Manganese, Vitamin D, Glucosamine, chondroitinsulfate, Methylsulfonylmethane (MSM), collagen serrata)' reason for change: New Information	(b) (4), (b) (6)	23 Aug 2020 15:00:06
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	18 Aug 2020 12:43:19
Data point term sent to Coder	System	14 Aug 2020 16:39:22
User entered 'Osteobiflex'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Bilateral Knee Osteoarthritis'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'twice daily (BID)'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:49:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:39:01
User entered 'UN Jan 2020'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:39:01

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:00
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:56 24 Nov 2020 17:14:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:41:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:41:24
Data point term sent to Coder User entered 'Crestor'	System (b) (4), (b) (6)	14 Aug 2020 16:40:25 14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '10'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:49:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:39:43
User entered 'UN UNK 2010'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:39:43

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 17:57:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:57:01
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:56 24 Nov 2020 17:14:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 09:58:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 09:58:35
Data point term sent to Coder	System	23 Aug 2020 15:01:53
User closed query 'For coding purposes, references indicate different formulations for PROTONIX. Please provide generic ingredients, complete, accurate trade name and update the term with your response.' (Site from System).	System	23 Aug 2020 15:01:39
Query 'For coding purposes, references indicate different formulations for PROTONIX.	(b) (4), (b) (6)	23 Aug 2020 15:01:39

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
Please provide generic ingredients, complete, accurate trade name and update the term with your response.' answered with 'active ingredients added' (Site from System).		
User entered 'PROTONIX (pantoprazole)' reason for change: New Information	(b) (4), (b) (6)	23 Aug 2020 15:01:31
User opened query 'For coding purposes, references indicate different formulations for PROTONIX. Please provide generic ingredients, complete, accurate trade name and update the term with your response.' (Site from System).	Coder Import (b) (4)	14 Aug 2020 19:35:24
Data point term sent to Coder	System	14 Aug 2020 16:41:28
User entered 'Protonix'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Acid Reflux'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '40'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:49:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:40:28
User entered 'UN UNK 2010'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:40:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:01
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:56 24 Nov 2020 17:14:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:42:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:42:18
Data point term sent to Coder User entered 'Vitamin D3'	System (b) (4), (b) (6)	14 Aug 2020 16:41:31 14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Nutritional Supplement'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '2000'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'IU (IU)'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:49:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:41:07
User entered 'UN UNK 2008'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:41:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:07
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:57 24 Nov 2020 17:14:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:43:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:43:21
Data point term sent to Coder User entered 'Oxybutinin'	System (b) (4), (b) (6)	14 Aug 2020 16:42:34 14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Overactive Bladder'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '10'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 21:49:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:42:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:41:52
User entered 'UN Jun 2019'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:41:52

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:01
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:57 24 Nov 2020 17:14:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 15:41:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 15:41:27
Data point term sent to Coder User entered 'Probiotic'	System (b) (4), (b) (6)	19 Aug 2020 15:40:12 19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Irritable bowel syndrome'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:27:46
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:39:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:39:20
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:53
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:39:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
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)	30 Dec 2020 14:30:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 14:30:31
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	30 Dec 2020 14:29:45 30 Dec 2020 14:29:05
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)	24 Nov 2020 17:55:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:55:07
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	24 Nov 2020 17:14:57 24 Nov 2020 17:14:53
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)	14 Nov 2020 00:24:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 00:24:37
Data point term sent to Coder User entered 'TYLENOL'	System Diandra Henriques (b) (4)	14 Nov 2020 00:23:41 14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
User closed query 'Per ETRTR: Medication is dosed during COVID-19 AE period. Please confirm whether this medication was dosed for a COVID-19 Symptom. If so, please go to COVID-19 AE page and state that medication was dosed, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 15:47:44
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 14:29:05
User entered 'HEADACHE, COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 14:29:05
Query 'Per ETRTR: Medication is dosed during COVID-19 AE period. Please confirm whether this medication was dosed for a COVID-19 Symptom. If so, please go to COVID-19 AE page and state that medication was dosed, thanks.' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 16:37:19
User opened query 'Per ETRTR: Medication is dosed during COVID-19 AE period. Please confirm whether this medication was dosed for a COVID-19 Symptom. If so, please go to COVID-19 AE page and state that medication was dosed, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 17:50:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:53
User entered 'HEADACHE'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '1000'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'mg (mg)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'twice daily (BID)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Oral (ORAL)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '11 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered '0'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:14:53
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Nov 2020 00:23:36

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE;GLUCOSAMINE SULFATE;METHYLSULFONYLMETHANE, PRODUCTSYNONYM: GLUCOSAMINE, CHONDROITIN & MSM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 14:13:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 14:13:03
Data point term sent to Coder	System	23 Apr 2021 16:10:25
User entered 'Glucosamine 1500mg, Vitamin C 60mg, Methylsulfonylmethane (MSM)/Chondroitin 1.1 g,manganese 2 mg'	(b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Bilateral knee osteoarthritis'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'un Jan 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:10:18

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:14:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:14:48
Data point term sent to Coder	System	23 Apr 2021 16:13:29
User entered 'Victoza'	(b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Diabetes Type 2'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '1.8'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:13:28

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:16:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:16:48
Data point term sent to Coder	System	23 Apr 2021 16:15:29
User entered 'Vitamin C'	(b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Nutritional supplement'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '1000'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:14:31

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:17:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:17:56
Data point term sent to Coder	System	23 Apr 2021 16:16:32
User entered 'Zinc'	(b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'nutritional supplement'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '100'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:15:53

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:20:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:20:50
Data point term sent to Coder	System	23 Apr 2021 16:19:34
User entered 'melatonin'	(b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Anxiety'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:07

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:28:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:28:52
Data point term sent to Coder	System	23 Apr 2021 16:20:36
User entered 'oxycodone'	(b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'left knee pain post surgical'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '05 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:56

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
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.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:23:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:23:01
Data point term sent to Coder	System	23 Apr 2021 16:21:37
User entered 'Tylenol'	(b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'left knee pain post surgical'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '1000'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '05 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:20:40

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:23:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:23:01
Data point term sent to Coder	System	23 Apr 2021 16:21:37
User entered 'Zofran'	(b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'vomiting'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '4'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:21:20

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:24:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:24:02
Data point term sent to Coder	System	23 Apr 2021 16:22:38
User entered 'Meclizine'	(b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'vertigo'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '25'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:22:04

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:25:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:25:01
Data point term sent to Coder	System	23 Apr 2021 16:23:40
User entered 'influenza vaccine'	(b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'influenza prophylaxis'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0.5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User entered empty.	System	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User entered empty.	System	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:11:46
User entered empty.	System	23 Apr 2021 16:22:54

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:55:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:34
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:41:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 15:41:34
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:49:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:04
User entered 'No (N)'	(b) (4), (b) (6)	12 Sep 2020 17:05:52

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:43:44

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'TOTAL left knee replacement'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:43:44

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:43:44

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:43:44

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:20

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'CT scan'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:20

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:20

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:20

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:36

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'ultrasound'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:36

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:36

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:36

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:59

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'CT scan'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:59

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:59

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:44:59

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:45:28

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Bone density dexa scan'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:45:28

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:45:28

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:45:28

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:11

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Aug 2021 22:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Magnetic resonance imaging (MRI)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:11

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:11

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Aug 2021 22:55:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:11

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Aug 2021 22:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:35

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Aug 2021 22:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Positron emission tomography (PET)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:35

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Aug 2021 22:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:35

US3592127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Aug 2021 22:55:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:46:35

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'USA-US103-2020-MRNA-1273-P301000010'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Terry'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Poling'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '1709 S Rock Rd'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Wichita'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'KS'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '67207'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:41:07
User entered 'US'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 13:52:47
User entered '3'	System	10 Dec 2020 18:18:26
User entered '2'	System	20 Nov 2020 14:41:54
User entered '1'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'USA-US103-2020-MRNA-1273-P301000010'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Terry'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Poling'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '1709 S Rock Rd'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Wichita'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'KS'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '67207'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:41:07
User entered 'US'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 13:52:47
User entered '3'	System	10 Dec 2020 18:18:26
User entered '2'	System	20 Nov 2020 14:41:54
User entered '1'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:55:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
User entered '19/Nov/2020 14:12'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:55:16

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.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:41:07
User entered 'l'	(D) (4), (b) (6)	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'USA-US103-2020-MRNA-1273-P301000010'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Terry'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Poling'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '1709 S Rock Rd'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Wichita'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'KS'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '67207'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:41:07
User entered 'US'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 13:52:47
User entered '3'	System	10 Dec 2020 18:18:26
User entered '2'	System	20 Nov 2020 14:41:54
User entered '1'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:55:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
User entered '20/Nov/2020 14:41'	System	20 Nov 2020 14:41:54

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:55:16

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.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	10 Dec 2020 18:18:12
DataPoint Verified.	(D) (4), (D) (6)	24 Nov 2020 17:13:50
User entered 'l'	(b) (4), (b) (6)	20 Nov 2020 14:41:54

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'USA-US103-2020-MRNA-1273-P301000010'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Terry'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Poling'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '1709 S Rock Rd'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Wichita'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'KS'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '67207'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:41:07
User entered 'US'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 13:52:47
User entered '3'	System	10 Dec 2020 18:18:26
User entered '2'	System	20 Nov 2020 14:41:54
User entered '1'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:55:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '10/Dec/2020 13:18'	System	10 Dec 2020 18:18:26

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:55:16

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.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 13:52:38
User entered 'l'	(b) (4), (b) (6)	10 Dec 2020 18:18:26

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'USA-US103-2020-MRNA-1273-P301000010'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:12:18
User entered 'No (N)'	System	19 Nov 2020 14:10:52

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Terry'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Poling'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '1709 S Rock Rd'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'Wichita'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'KS'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '67207'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Nov 2020 17:13:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:41:07
User entered 'US'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 13:52:47
User entered '3'	System	10 Dec 2020 18:18:26
User entered '2'	System	20 Nov 2020 14:41:54
User entered '1'	System	19 Nov 2020 14:12:36

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:55:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered '20/Jan/2021 08:52'	System	20 Jan 2021 13:52:47

US3592127

Folder: SAE USA-US103-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:55:16

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.	Terry Poling (b) (4)	28 Apr 2021 07:28:51
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:58:31
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 13:52:47